

# **EXHIBIT D**

# Deposition Transcript of William J. Vigilante, Jr., Ph.D., CPE (09.23.16)

PAGE:LINE(S) CITED IN MEMORANDUM OF LAW
--

410:8-12
----------

VOLUME II  
 UNITED STATES DISTRICT COURT  
 FOR THE DISTRICT OF CONNECTICUT

RACHEL DENNERT,

Plaintiff,

-vs-

MEDTRONIC, INC.;

MEDTRONIC MINIMED,

INC., d/b/a MEDTRONIC

DIABETES, a Division of

MEDTRONIC, INC.

(improperly named as

MEDTRONIC DIABETES);

UNOMEDICAL DEVICES SA

de CV and UNOMEDICAL

A/S,

Defendants.

Civil Action No.

3:11-CV-01229 (SRU)

WILLIAMS CUKER BEREZOFSKY  
 1515 MARKET STREET - SUITE 1300  
 PHILADELPHIA, PENNSYLVANIA 19102  
 SEPTEMBER 23, 2016  
 10:27 A.M.

CONTINUED VIDEOTAPED DEPOSITION OF  
 WILLIAM J. VIGILANTE, JR., Ph.D., CPE

REPORTED BY:

DEBRA SAPIO LYONS, RDR, CRR, CRC, CCR, CPE

JOB NO. 112521

Page 271

September 23, 2016

Continued videotaped deposition of William J. Vigilante, Jr., Ph.D., CPE, held at the offices of Williams Cuker Berezofsky, 1515 Market Street, Suite 1300, Philadelphia, Pennsylvania 19102, before Debra Sapio Lyons, a Registered Diplomat Reporter, a Certified Realtime Reporter, a Certified Realtime Captioner, a Certified LiveNote Reporter, an Approved Reporter of the United States District Court for the Eastern District of Pennsylvania, a Certified Court Reporter of the State of New Jersey, a Notary Public of the States of New Jersey, New York and the Commonwealth of Pennsylvania.

Page 272

APPEARANCES:

WILLIAMS CUKER BEREZOFSKY  
BY: ALAN SKLARSKY, ESQUIRE  
Woodland Falls Corporate Center  
210 Lake Drive East  
Cherry Hill, New Jersey 08002  
Attorneys for Plaintiff Rachel Dennert

MASLON

BY: DAVID SCHULTZ, ESQUIRE  
(Present via Videoconference)  
3300 Wells Fargo Center  
90 South Seventh Street  
Minneapolis, Minnesota 55402  
Attorneys for Defendant Medtronic, Inc.;  
MEDTRONIC MINIMED, INC., d/b/a MEDTRONIC  
DIABETES, a Division of MEDTRONIC, INC.  
(improperly named as MEDTRONIC DIABETES)

THOMPSON HINE

BY: Z. ILEANA MARTINEZ, ESQUIRE  
(Present via Videoconference)  
Two Alliance Center  
3560 Lenox Road  
Atlanta, Georgia 30326  
Attorneys for Defendant Unomedical  
Devices SA de CV and Unomedical A/S

ALSO PRESENT:

GERARD ALFE, LEGAL VIDEO SPECIALIST  
TSG REPORTING

Page 273

W. VIGILANTE

THE VIDEOGRAPHER: This video deposition is now continuing. The witness has been previously sworn. His name is William J. Vigilante, Jr.

Please continue.

MR. SCHULTZ: Good morning, Mr. Vigilante.

THE VIDEOGRAPHER: Oh, excuse me. I'm sorry. The date is September 23rd, 2016. The time 10:27.

WILLIAM J. VIGILANTE, JR., Ph.D., CPE, having been previously sworn, was examined and testified as follows:

EXAMINATION

BY MR. SCHULTZ:

Q. Good morning, Mr. Vigilante. This is David Schultz from the Maslon firm in Minneapolis.

Can you hear me?

A. Yes.

Q. Okay. Thank you.

Mr. Vigilante, have you done, other than coming for this deposition, have you done additional work on this case since we

Page 274

W. VIGILANTE

first started your deposition?

A. Yes.

Q. What have you done?

A. I reviewed my deposition transcript and I reviewed my file to prepare to come to today, and then I spoke with Mr. Haverty.

Q. Okay. Am I correct in assuming that you have not changed or modified your opinions since last we spoke?

A. Correct.

Q. Okay. And having reviewed your testimony, did you see anything in your testimony that you felt needed to be corrected or clarified?

A. I don't think so.

Q. Okay. All right. I want to go back and just finish up briefly on some of the material we were talking about on the Medtronic human factors analysis that was undertaken during the design process for the P-cap; and I don't want to revisit all of your opinions or retread all of the testimony, but at least as I recall it from your report, one

Page 275

1 W. VIGILANTE

2 of the criticisms that I think you had is that  
3 the human factors or use analysis -- or the  
4 use study -- usability study that was done at  
5 the time in or around 2000 was, in your  
6 opinion, deficient in part because the IFU  
7 that was used with the test subjects was  
8 different from the IFU that was eventually  
9 shipped with the products to Rachel Dennert.

10 Is that a fair summary?

11 A. Yes, the -- the IFUs that were  
12 tested and the process for filling the  
13 reservoir that was tested was changed from the  
14 time that those studies were done to the IFU  
15 and process that was presented to  
16 Mrs. Dennert.

17 Q. Okay. And one way in which I  
18 think you said the IFU was different was that  
19 the IFU that was used for testing depicted the  
20 insulin vial at the point of removal of the  
21 reservoir, depicted it on a table or surface  
22 when the reservoir is removed, and that that  
23 depiction is not carried forward into the IFU  
24 that was shipped with Rachel Dennert.

25 Do I have that right?

Page 276

1 W. VIGILANTE

2 A. I believe so.

3 Q. Okay. But we don't have -- that's  
4 a description that -- that is given, but  
5 neither you nor I have seen that test IFU;  
6 correct?

7 A. Yeah, that IFU has not been  
8 provided in discovery. The --

9 Q. You're aware --

10 A. The -- I'm sorry.

11 Q. -- that during the use of -- I'm  
12 sorry.

13 A. I was going to say that there were  
14 multiple IFUs that were tested and none of  
15 them were -- multiple versions of the IFU that  
16 were tested or assessed in the usability  
17 studies, and none of them were -- were  
18 produced in discovery.

19 Q. Okay. And if Medtronic says they  
20 don't exist, you have no reason to quarrel  
21 with that, do you?

22 A. I wouldn't know.

23 Q. Okay. One of the things -- let me  
24 stop for a second.

25 MR. SCHULTZ: Ileana, I can see

Page 277

1 W. VIGILANTE

2 you're having some difficulties.

3 THE WITNESS: I think she just went  
4 away.

5 MR. SKLARSKY: We lost her at this  
6 end.

7 MR. SCHULTZ: We just lost her here  
8 too. Why don't we go off the record and  
9 wait. Sorry.

10 THE VIDEOGRAPHER: We're now going  
11 off the video record. The time 10:31.

12 (A recess is held from 10:31 a.m. to  
13 10:32 a.m.)

14 THE VIDEOGRAPHER: Back on 10:32.

15 BY MR. SCHULTZ:

16 Q. Mr. Vigilante, you're aware that  
17 during the usability studies that were  
18 performed by Medtronic in 2000 or thereabouts  
19 during the development of the P-cap, none of  
20 the users who were part of that study were  
21 reported to have removed the reservoir from  
22 the insulin vial with the insulin vial above  
23 the reservoir; correct?

24 A. Yes.

25 Q. Do you attribute that to the

Page 278

1 W. VIGILANTE

2 belief that the original IFU that was used in  
3 the usability study physically depicted the  
4 vial on the table at the time the reservoir  
5 would then be removed from the transfer guard?

6 A. In part.

7 Q. Okay. What else do you attribute  
8 it to?

9 A. Well, the fact is the IFU -- the  
10 IFUs that were tested based upon their  
11 description in McConnell's deposition, the  
12 insulin vial never left the table. So it was  
13 placed on the table, connected to the transfer  
14 guard and reservoir, air pumped into it,  
15 medication removed from it into -- or  
16 transferred into the reservoir, and the  
17 reservoir removed from the transfer guard all  
18 with the insulin vial on the table, so it was  
19 never removed from the table.

20 Q. Okay.

21 A. So second -- the second part is,  
22 is that the study was done with employees of  
23 the Clinical Services Department, and I don't  
24 have any information on whether or not those  
25 folks had any inclination or were aware of the

Page 279

W. VIGILANTE

potential problems with doing the task any other way. Again, this wasn't a representative sample of the user population, so we don't know if that affected the -- their actions and -- and so forth.

Q. Okay. If -- if the IFU that had been shipped with Rachel Dennert's devices had depicted the reservoir -- or rather the insulin vial on the table at the time the reservoir is removed, would that have been adequate in your view?

A. No.

Q. Why not?

A. Well, first, it depends on what the prior steps were, but more importantly, it needed a warning to let folks know that the potential for any fluid, including the insulin, getting on the top of the reservoir or contaminating the bottom of the -- the P-cap was problematic and can lead to serious injury.

Q. Would the -- would you agree -- set aside the question of warning for a second. Would you agree that if the IFU

Page 280

W. VIGILANTE

shipped with Rachel Dennert's devices depicted the vial on the table when the reservoir is removed from it as an instruction, would that have been clear? Not as a warning. We'll get to that side of it, but...

A. It -- it depends on what the prior steps were and the other steps were and then also how it was depicted.

Q. Okay. Can you elaborate on that?

A. Well, you're asking me to give an answer to a hypothetical. I mean, this could be the worst IFU in the world ever developed, and in Step 6 it shows or attempts to show that the vial is sitting on a table. So I can't give you an opinion that that hypothetical IFU would have been appropriate or not. Without seeing it, you know, you -- you can't make a assessment based upon a single step without understanding the totality of the other steps and the way it's presented.

Q. Okay. So you can't -- you can't opine on whether a step showing the reservoir being detached with the vial actually on the table, as to whether that would be clear and

Page 281

W. VIGILANTE

adequate to instruct the user whether to remove the reservoir from above the vial?

MR. SKLARSKY: Note an objection. I'm not sure you're restating his testimony quite as he gave it.

And the only other thing, Dave, do you -- do you have -- since you're describing a particular IFU, and I realize I'm, you know, a newcomer to the case, do you -- do you have such a document that can be shown to him that you're describing?

MR. SCHULTZ: Well, the documents are what they are in the case. I'm just asking if you can answer the question as asked.

MR. SKLARSKY: So as -- as a hypothetical at this point?

MR. SCHULTZ: Go ahead.

A. Yeah, the -- based upon the information you've given me, I don't have enough information to -- to make an assessment.

Q. Okay.

A. It's an incomplete hypothetical.

Page 282

W. VIGILANTE

Q. If -- if you would look at --

MR. SCHULTZ: Madame Court Reporter, if you would hand Mr. Vigilante Exhibit Number 11, which is his supplemental report dated June 16th of 2016.

THE WITNESS: Thank you.

(Exhibit Vigilante-11, letter dated June 16, 2016 addressed to Kevin Haverty, Esq., was previously marked for identification.)

COURT REPORTER: He has it.

MR. SCHULTZ: Thank you.

Q. Doctor, just directing your attention to Page 1 of your report, the supplemental report, Exhibit 11, I just want to make sure I'm clear on what is being communicated here. In the last paragraph on the first page we're talking about this issue of the IFU that was shipped with the devices having been changed after the second usability study, and you write in that paragraph, "Although Medtronic was aware of this potential," referencing above, "they changed the IFU after the human factors studies."

Page 283

W. VIGILANTE

And your basis for that is the statement, or the deposition testimony of Susan McConville, correct -- or McConnell?

A. Yeah, the -- I'm referring back to Mrs. McConnell Mon -- Montal -- Montal -- I'm sorry. I don't know how to pronounce her last name -- deposition testimony for that sentence, but I also know that the IFU that was shipped with Ms. Dennert's infusion set was different than the ones they tested.

Q. Okay. And I just want to make clear you're relying on the testimony of Susan McConnell for that as opposed to something that you, yourself, have viewed; correct?

A. I don't understand the question. So can you rephrase it, please?

Q. Sure. I'm just trying to make sure I have your opinion which is based on the testimony of Susan McConnell; right?

A. In part.

Q. On this -- on this aspect of the change of the IFU?

A. Well, in part. I mean, the -- the exhibits to her deposition included the

Page 284

W. VIGILANTE

usability study, and the usability -- excuse me, the usability study described the IF -- described in part the IFUs that were provided or were assessed during those studies. And then I also --

Q. Right.

A. -- had the IFU that was included in the infusion set that Mrs. Dennert was using.

Q. Right.

A. So I think based upon the testimony, the exhibits, and the -- the subject IFU, I can support those statements.

Q. Okay. Fair enough. I'm just trying to understand. I mean, so you had the usability studies and you have the current IFU and Ms. McConnell's testimony about those documents; correct?

A. Yes.

Q. Okay. In the IFU that was shipped with Rachel Dennert's devices, are you -- they depict, among other things, hands that are holding the reservoir and insulin vial;

Page 285

W. VIGILANTE

correct?

A. Yes.

Q. Is it your belief that that depiction instructs the user that they should use the particular hands in the particular orientation as depicted?

In other words, if the IFU depicts the person in the -- in the graphic using the right hand to remove the reservoir, is it your understanding that the IFU is commanding that person or directing that person that they have to use their right hand to remove the reservoir?

A. Well, we talked about this last time. The answer is yes and no.

Q. Okay. Explain that to me, would you?

A. Sure. The IFU depicts the strong hand as the right hand, so certainly left-handed people would naturally reverse it. I think that's the -- the way it's typically done. When you're giving people fine motor skills and you're giving them instructions regarding those fine motor skills, they

Page 286

W. VIGILANTE

reverse it because, you know, they're a minority in the -- in the world and they understand that typically the instructions are -- are done for right-handed strong hand folks.

Second is that the IFU doesn't tell you whether or not you have to do it exactly the way it's depicted, but we know that if you don't do it exactly as it's depicted in at least some of the steps, there are really severe catastrophic consequences. So it's either it doesn't matter whether you follow the IFU exactly or you have to follow it exactly; and in this IFU, Mini-Med hasn't made it clear what the -- what the intent and purpose is.

So you're arguing that Ms. Dennert did it wrong, but there's nothing in here that says you have to do it exactly. So you can't argue and have it both ways. Either you have to follow it exactly or you have leeway; and either way it's not a very good IFU.

Q. Isn't there really a middle ground, though, that the IFU communicates what

Page 287

W. VIGILANTE

steps you have to do such as removing the reservoir from the vial with the reservoir above, but naturally leaves it to the user to figure out which hand they'd prefer to do that step with; isn't that a fair interpretation?

A. That might be your interpretation, but that's a -- that's a terrible way to do instructions. So either you're allowing the user to make assumptions and to use their own preferences or you tell them they have to do it exactly like this because if you don't do it exactly like this, there's catastrophic consequences.

So you can't have it either way. You can't say, well, they can kind of do what they want in some of the steps and within a step they can do it the way they want, but on Step 6 they have to have the vial -- the insulin vial under the reservoir because you can possibly die if you don't. You can't have it both ways, and, you know, that was one of the things I tried to explain in the last deposition.

Q. Well, what I was getting at is

Page 288

W. VIGILANTE

that -- this is a simple question. Either you agree or you don't agree, and I suspect I know your answer. But isn't it the case that it's -- that the IFU is communicating "Take the reservoir, remove it from the transfer guard with the vial beneath the reservoir," but that even though it shows somebody doing that, it's not saying "And you have to use this particular hand to do it"? Isn't the -- the point of the instruction the relationship between the reservoir and the vial?

A. Again, there's no intention identified on the IFU for what Medtronic and Unomedical intended. So did they intend it to be followed literally or did they intend it to be followed figuratively with preferences to the user? Again, it's not communicated. But we do know that if you don't follow Step Number 6 in flipping it, it produces catastrophic -- potentially catastrophic damages, but there's nothing to alert you to the fact that that's the case; and there's nothing to alert you to the fact that if you want to change hands, that's okay, but if you

Page 289

W. VIGILANTE

want to change orientation, that's absolutely not okay. So, again, it's not -- it's not the right way to do instructions.

MS. MARTINEZ: Object to the answer.

Move to strike.

MR. SCHULTZ: Join the objection.

Q. Well, let's -- let's do this doc -- Mr. Vigilante. Let's turn to your first report.

MR. SCHULTZ: Madame Court Reporter, I believe it was previously marked as Deposition Exhibit Number 10.

(Exhibit Vigilante-10, Report of William J. Vigilante, Jr., PhD, CPE dated April 19, 2016, was previously marked for identification.)

COURT REPORTER: He has it.

MR. SCHULTZ: Thank you.

Q. Mr. Vigilante, if you would turn to Page 19 of your report, Exhibit Number 10?

A. (The witness complies with the request of counsel.)

Okay.

Q. In the fourth full paragraph on

Page 290

W. VIGILANTE

that page you write, (as read): "Medtronic and Unomedical's failure -- Unomedical's failure to provide adequate instructions and warning was improper and unreasonably dangerous, rendered the Paradigm reservoir and infusion set defective and unreasonably dangerous, and caused Rachel Dennert's injury."

You see that?

A. Yes.

Q. Can you explain how it caused Rachel Dennert's injury?

A. Yeah, I'm relying upon Michael Klimowicz's analysis that the -- that the -- Mrs. Dennert experienced a -- an uncontrolled and unknown injection of insulin due to the anomaly associated with the blockage of the vents and that that unknown injection of insulin caused the -- the injuries that she suffered.

Q. Okay. And aren't you also -- maybe you're not.

Are you also testifying that the reason that Rachel Dennert experienced

1 W. VIGILANTE

2 temporarily blocked vents on the P-cap is  
3 because she removed the reservoir -- reservoir  
4 from beneath the vial and that that was a  
5 result -- her decision to do that or her  
6 practice in doing that was because of  
7 something about the IFU?

8 A. Yeah, I'm sorry. I thought we  
9 were -- we were focussed on the -- the injury  
10 causation as opposed to the event causation.  
11 So the failure to provide adequate  
12 instructions and warnings deprived her of the  
13 information she needed to, to use the infusion  
14 set and reservoir correctly and prevent the  
15 fluid, including insulin, from getting on the  
16 top of the reservoir and contaminating the  
17 underside of the P-cap.

18 Q. Yeah. And I'm -- what I'm asking  
19 then is for you to explain how it is that  
20 what you opine as the inadequacy of the  
21 infusion set, or the IFU for the reservoir  
22 rather, caused this to happen?

23 MR. SKLARSKY: Dave, didn't he -- I  
24 thought he just answered that question.  
25 It's the same question.

1 W. VIGILANTE

2 listen, I just didn't hear him. Okay?

3 MR. SKLARSKY: Okay.

4 MR. SCHULTZ: I'll -- be patient  
5 with me. I haven't done this by video  
6 conference before. I thought he was done.

7 MR. SKLARSKY: Okay.

8 THE WITNESS: Yeah, that's okay.

9 I kind of lost my train of thought.

10 A. So it's my understanding  
11 Dr. Klimowicz has determined the manner in  
12 which the insulin was allowed to flow  
13 uncontrolled and unexpected was due to the  
14 blockage of the vents. Whether it was insulin  
15 or another contaminant, I don't know for sure.  
16 The insulin seems to be the -- the most  
17 likely, but I can't rule out that there was  
18 another -- another contaminant. I think  
19 the -- that's the -- that's the easiest way to  
20 put it.

21 Q. Yeah, and I -- I'm really asking  
22 you a different question. So let me -- let me  
23 back up and we'll come at it a different way.

24 First of all, in your -- in your  
25 report you distinguish between instructions

1 W. VIGILANTE

2 MR. SCHULTZ: Well, I'm sorry. If  
3 I -- if I missed it, I missed it, but I  
4 didn't hear that.

5 A. Yeah. I'm sorry. The IFU and --  
6 the IFUs failed to provide adequate warning to  
7 alert Rachel Dennert on how to do the steps  
8 properly to prevent insulin from getting on  
9 the top of the reservoir before she puts it on  
10 the P-cap, and it failed to instruct her,  
11 informed her to ensure that there was no  
12 contaminant on top of the reservoir before  
13 connecting it to the P-cap. So, again,  
14 Mr. Klimowicz -- Dr. Klimowicz has opined that  
15 the prime fill anomaly was caused by the  
16 blockage of the -- of the cap, of the vents on  
17 the P-cap. So the vents --

18 Q. Yeah, I understand that part.

19 A. The vents --

20 Q. I guess what I'm --

21 (Reporter clarification -  
22 simultaneous speaking.)

23 MR. SKLARSKY: Yeah, let him finish,  
24 so you can then ask the next question.

25 MR. SCHULTZ: I'm sorry. You know,

1 W. VIGILANTE

2 and warnings; correct?

3 A. Well, I define instructions and I  
4 define warnings. Sometimes instructions have  
5 warnings and sometimes warnings have  
6 instructions.

7 Q. So what's the -- what's the  
8 difference?

9 Well, am I right that an  
10 instruction tells a user how to do something  
11 and a warning gives the user information about  
12 the danger of doing it or not doing it a  
13 certain way --

14 A. Yeah, typ --

15 Q. -- or following or not following  
16 instructions?

17 A. Yeah, typically instructions are  
18 provided to inform somebody how to do  
19 something the proper way to do it, the correct  
20 way to do it; and if there are hazards  
21 associated with the improper way of doing it  
22 or even hazards associated with the proper way  
23 of doing it, warnings call attention to the  
24 presence of the hazard, identify it, alert the  
25 user to the hazard, identify what it is, and

Page 295

W. VIGILANTE

what's needed to be done to avoid it, which may be, for example, ensuring that the instructions are followed to the T.

Q. So am I correct in understanding as a global matter your opinions are -- you -- you would agree that the IFU provided instructions, you -- your opinion is they were not adequate, but did not provide a warning; is that a fair summary?

A. Yeah, the IFU provided instructions. There were no warnings on the IFU related to the topic. The instructions provided by the IFU were inadequate.

Q. Okay. Do you have any evidence that at the time Rachel Dennert changed out her infusion set at approximately ten o'clock or eleven o'clock on August 8th of 2009, that she had the vial above the reservoir when she filled the reservoir and then removed it?

A. Yeah, I -- I don't have any evidence to -- to state that that's exactly what happened. We do know that her mother didn't see anything wrong with what she did, but I don't have any testimony from her mom

Page 297

W. VIGILANTE

with this prime fill anomaly and how it was discovered by Medtronic, is that is holding the insulin vial over the reservoir when detaching the reservoir, there were no warnings or instructions in the IFU to alert folks or readers that the reservoir needed to be on top, that it -- those -- that -- that step was not clear. It was not called out. There was no text to -- to -- to go with it to let the user know or ensure the user knows that it needs to be flipped. There were no warnings regarding the hazard associated with it or getting any contaminant on the top of the reservoir before connecting it to the P-cap.

And then we have the number of prime fill anomalies that were recorded by Medtronic going back to I think, like, 2002.

We have the YouTube videos showing people doing exactly what you would expect them to do based upon the natural way of filling and removing the reservoir from the transfer guard and the insulin vial.

So I think the totality of that,

Page 296

W. VIGILANTE

saying that she saw her remove it in a certain way or a certain sequence.

Q. Okay. Assuming that she did it that way, do you have any evidence that she did it that way because of the unclarity or deficiencies, as you opine it, of the IFU for the reservoir?

MR. SKLARSKY: I have an objection to the form. I think it's somewhat a compound question and somewhat confusing, but he can answer.

A. Yes, there's -- there's multiple pieces of evidence.

Q. Okay. What's the evidence that assuming Rachel Dennert removed the reservoir from the vial with the reservoir beneath it at that time, that was a result of the content of the IFU, what's your evidence for that?

A. So my understanding is, is that she had the IFUs, her mother said that she was using the -- the one sheet instructions for doing the infusion set as opposed to relying upon the larger manual. The natural way of doing it is, again, the way that is associated

Page 298

W. VIGILANTE

along with my analysis, is the evidence that I relied upon.

Q. Would you agree that YouTube videos are not direct evidence of what Rachel Dennert did or didn't do on August 8th in 2009?

MR. SKLARSKY: Objection to the form, but go ahead.

A. Yeah, I mean it's indirect evidence. It's supporting the fact that the natural way to do it is what was depicted in -- in those YouTube videos that we discussed at the last deposition.

Q. Is it your testimony that the YouTube videos explain what Rachel Dennert did and why she did it?

A. I think it's just part of the overall evidence and facts that lead to the conclusion that the natural way to do it is to remove the reservoir from under the insulin vial; and there's nothing to suggest that Rachel Dennert knew differently or her mother knew differently. She wasn't trained on the hazard either by the -- the trainer or her

<p style="text-align: right;">Page 299</p> <p>1 W. VIGILANTE</p> <p>2 doctor because Medtronic and Unomedical never</p> <p>3 bothered to train the doctor and their</p> <p>4 educators and trainers on the importance of</p> <p>5 this one step and the hazard associated with</p> <p>6 getting contaminants on the top of the</p> <p>7 reservoir.</p> <p>8 Q. Is it your opinion that Uno --</p> <p>9 MS. MARTINEZ: Object, move to</p> <p>10 strike. I'm sorry. Object to the form.</p> <p>11 Move to strike.</p> <p>12 Q. Is it your understanding that</p> <p>13 Unomedical provides training to Medtronic pump</p> <p>14 patients?</p> <p>15 A. I'm understanding that Medtronic</p> <p>16 does. I'm not sure exactly Unomedical's</p> <p>17 participation and whether or not the -- the</p> <p>18 trainers are trained and provided it to the</p> <p>19 potential patients.</p> <p>20 Q. Okay. Let's shift gears a little</p> <p>21 bit. I'll come back to this topic in a</p> <p>22 minute, but do I understand one -- one of the</p> <p>23 opinions in your report is that it was</p> <p>24 unreasonable of Medtronic or improper of</p> <p>25 Medtronic to rely upon the instructions that</p>	<p style="text-align: right;">Page 300</p> <p>1 W. VIGILANTE</p> <p>2 are contained in the pump user guide?</p> <p>3 Do I have that right?</p> <p>4 A. For this particular hazard, yes.</p> <p>5 Q. Right. Okay.</p> <p>6 MR. SCHULTZ: Madame Court Reporter,</p> <p>7 would you hand Mr. Vigilante Exhibit Number</p> <p>8 12, the pump user guide?</p> <p>9 THE WITNESS: Thank you.</p> <p>10 MR. SKLARSKY: Dave, could I just --</p> <p>11 Q. So, Mr. Vigilante --</p> <p>12 MR. SKLARSKY: Dave. Dave.</p> <p>13 MR. SCHULTZ: Yeah.</p> <p>14 MR. SKLARSKY: Dave, hold on one</p> <p>15 second. Can I just interpret for one</p> <p>16 minute? Is it -- was -- is this Exhibit 12</p> <p>17 for this deposition or for a different</p> <p>18 deposition?</p> <p>19 MR. SCHULTZ: I believe it was --</p> <p>20 oh, this -- I see. On this copy it was</p> <p>21 marked as Exhibit 12 during the deposition</p> <p>22 of Nancy Dennert, so we should probably</p> <p>23 mark it for this deposition which I think</p> <p>24 we're on 19 if I'm not mistaken.</p> <p>25 COURT REPORTER: Okay. Dwayne told</p>
<p style="text-align: right;">Page 301</p> <p>1 W. VIGILANTE</p> <p>2 me 18, but do you want me to check or not?</p> <p>3 MR. SKLARSKY: Yeah, no, I think --</p> <p>4 I think that's right. I printed out</p> <p>5 from -- that I -- we -- you went up -- at</p> <p>6 the last deposition I think 17 was the last</p> <p>7 exhibit; is that right?</p> <p>8 MR. SCHULTZ: Okay.</p> <p>9 MR. SKLARSKY: Yeah.</p> <p>10 MR. SCHULTZ: Why don't we mark this</p> <p>11 as 18. I think you're right, Alan.</p> <p>12 (Pause.)</p> <p>13 MR. SCHULTZ: Has it not been marked</p> <p>14 or not yet?</p> <p>15 COURT REPORTER: No.</p> <p>16 MR. SKLARSKY: Not -- not yet.</p> <p>17 MR. SCHULTZ: Okay.</p> <p>18 COURT REPORTER: I was just checking</p> <p>19 the previous transcript.</p> <p>20 MR. SKLARSKY: Is that right --</p> <p>21 MR. SCHULTZ: Oh, thank you.</p> <p>22 MR. SKLARSKY: -- 17? It was 17?</p> <p>23 It's 18.</p> <p>24 (Exhibit Vigilante-18, multipage</p> <p>25 document entitled Paradigm 522 and 722</p>	<p style="text-align: right;">Page 302</p> <p>1 W. VIGILANTE</p> <p>2 Insulin Pumps User Guide bearing Bates</p> <p>3 Numbers MDT000073RD through MDT000332RD, is</p> <p>4 marked for identification.)</p> <p>5 THE WITNESS: Thank you.</p> <p>6 COURT REPORTER: Okay. I've marked</p> <p>7 it as 18.</p> <p>8 BY MR. SCHULTZ:</p> <p>9 Q. All right. Mr. Vigilante, you now</p> <p>10 have what's been marked as Exhibit 18, which</p> <p>11 is the user guide that was produced with</p> <p>12 Rachel Dennert's pump, correct, as far as you</p> <p>13 know?</p> <p>14 A. Yeah, this seems to be a copy of a</p> <p>15 Paradigm 722 insulin pump, so I don't know if</p> <p>16 this is the exact copy that Mrs. Dennert had</p> <p>17 or if it's a exemplar produced by Medtronic.</p> <p>18 So whatever you want to do, I'll -- I'll be</p> <p>19 happy to go along.</p> <p>20 Q. Well, the record will be what the</p> <p>21 record is. I will represent to you that this</p> <p>22 is a copy of the user guide. It's not the</p> <p>23 specific one that was shipped obviously, but</p> <p>24 it is a copy of what was shipped with</p> <p>25 Ms. Dennert's pump, and I'll make that</p>

<p style="text-align: right;">Page 303</p> <p>1 W. VIGILANTE</p> <p>2 representation to you.</p> <p>3 A. Okay.</p> <p>4 Q. If you turn to Pages 60 and 61 of</p> <p>5 the user guide, you see that this is the</p> <p>6 section of the user guide --</p> <p>7 A. I'm sorry. I -- I haven't gotten</p> <p>8 there yet.</p> <p>9 MR. SKLARSKY: He's not quite there</p> <p>10 yet.</p> <p>11 A. It's a -- it's a big manual.</p> <p>12 Okay.</p> <p>13 Q. This is the section of the user</p> <p>14 guide that relates to removal -- well, filling</p> <p>15 the reservoir and then connecting it to the</p> <p>16 infusion set; correct?</p> <p>17 A. Yeah, the title of the section is</p> <p>18 "Filling the Reservoir."</p> <p>19 Q. Yeah. And on Page 61 there is a</p> <p>20 pictograph that has a Step 9 labeled.</p> <p>21 Do you see that?</p> <p>22 A. Yes, there is a pictograph with a</p> <p>23 Step 9.</p> <p>24 Q. Yeah. And that pictograph shows</p> <p>25 that the reservoir is being removed from the</p>	<p style="text-align: right;">Page 304</p> <p>1 W. VIGILANTE</p> <p>2 vial with the reservoir above the vial;</p> <p>3 correct?</p> <p>4 A. Yes.</p> <p>5 Q. And above that there is text that</p> <p>6 says, relating to Step 9, "With the vial down,</p> <p>7 hold the transfer guard. Turn the reservoir</p> <p>8 counterclockwise, then pull straight up to</p> <p>9 remove it from the transfer guard."</p> <p>10 Do you see that?</p> <p>11 A. Yes.</p> <p>12 Q. Would you agree with me that that</p> <p>13 description and combination with the</p> <p>14 pictograph makes it clear that the reservoir</p> <p>15 is to be removed from the insulin vial with</p> <p>16 the vial beneath the reservoir?</p> <p>17 A. It does a better job, certainly,</p> <p>18 than the IFU for the infusion set.</p> <p>19 Q. Well, that's not quite my</p> <p>20 question. I understand that's your opinion,</p> <p>21 but my question was: Do you agree that the</p> <p>22 language in combination with the pictograph</p> <p>23 makes it clear to the user that the reservoir</p> <p>24 is to be removed from the transfer guard with</p> <p>25 the vial beneath the reservoir? Is it clear?</p>
<p style="text-align: right;">Page 305</p> <p>1 W. VIGILANTE</p> <p>2 A. That's what the sentence says.</p> <p>3 Q. And do you agree that it clearly</p> <p>4 communicates that --</p> <p>5 A. Well --</p> <p>6 Q. -- to the user?</p> <p>7 A. -- yes and no.</p> <p>8 Q. Okay. How yes?</p> <p>9 A. That's what the sentence says.</p> <p>10 Q. And how no?</p> <p>11 A. Well, again, you're -- you're</p> <p>12 taking a -- a small part of the overall</p> <p>13 procedure and asking me to analyze it without</p> <p>14 the rest of the context. So much as we talked</p> <p>15 about the IFU at the beginning of this</p> <p>16 deposition, and the last deposition, there's</p> <p>17 no instruction here that says you have to do</p> <p>18 it exactly like this and there's no warning in</p> <p>19 here to tell you what the consequences are if</p> <p>20 you don't do it exactly like this.</p> <p>21 Q. All right. I want to --</p> <p>22 A. So the sentence itself --</p> <p>23 Q. I understand your --</p> <p>24 (Reporter clarification -</p> <p>25 simultaneous speaking.)</p>	<p style="text-align: right;">Page 306</p> <p>1 W. VIGILANTE</p> <p>2 Q. I'm sorry.</p> <p>3 A. Yeah. I'm sorry. Go ahead.</p> <p>4 Q. Okay. I -- I don't mean to</p> <p>5 interrupt you. I -- I'm not trying to do</p> <p>6 that.</p> <p>7 I understand there's not a warning</p> <p>8 in here about liquid that we've discussed. My</p> <p>9 question really was: The instruction itself</p> <p>10 is not ambiguous about what it's telling the</p> <p>11 user to do; correct?</p> <p>12 A. As I stated before, the sentence</p> <p>13 is clear.</p> <p>14 Q. Okay. Part of your opinion at</p> <p>15 least is that it's unreasonable for Medtronic</p> <p>16 to rely on the user guide, at least as I would</p> <p>17 understand it, that it's -- it's a big</p> <p>18 document and it's, you know, something that</p> <p>19 the user might not read; is that correct?</p> <p>20 A. No, I didn't say the user may not</p> <p>21 read it. I have a -- there's a discrepancy in</p> <p>22 how -- I've got a -- a note that the user</p> <p>23 guide is 250 pages long, and I don't know if</p> <p>24 it's just the way this copy is, maybe it's the</p> <p>25 way it's numbered, but it ends on Page 242, so</p>

<p style="text-align: right;">Page 307</p> <p>1 W. VIGILANTE</p> <p>2 I'm not sure why the discrepancy.</p> <p>3 Q. Well, let me ask you this,</p> <p>4 Mr. Vigilante.</p> <p>5 Is there any evidence that you're</p> <p>6 aware of that Rachel Dennert did not read this</p> <p>7 portion of the user guide?</p> <p>8 A. Yeah, I don't have any evidence</p> <p>9 that she did read or did not read this portion</p> <p>10 of the user guide.</p> <p>11 Q. Okay. Do you have any -- then I</p> <p>12 would assume it follows from that that you</p> <p>13 don't have any evidence that she didn't</p> <p>14 understand it if she had read it?</p> <p>15 A. Yeah, there's -- there's been no</p> <p>16 testimony on whether she read it or whether</p> <p>17 she understood it at the time she read it or</p> <p>18 not.</p> <p>19 Q. And there's no evidence that</p> <p>20 you're aware of that if she had read it, she</p> <p>21 didn't remember it at the time she was filling</p> <p>22 her reservoir on August 8th of 2009?</p> <p>23 A. Yeah, there's no testimony either</p> <p>24 way, but I highly doubt it, that she would, A,</p> <p>25 remember it if she did, in fact, read it.</p>	<p style="text-align: right;">Page 308</p> <p>1 W. VIGILANTE</p> <p>2 Q. Why do you doubt that?</p> <p>3 A. It's 250 pages long. As soon as</p> <p>4 you get to the next couple pages in the</p> <p>5 manual, you're going to forget what you had</p> <p>6 just read a few pages back. There is an awful</p> <p>7 lot of information in this manual and</p> <p>8 Medtronic provides an IFU that's specific to</p> <p>9 the task. So typically people are going to</p> <p>10 look for the shorter instructions that are</p> <p>11 specific to a task, as opposed to go back and</p> <p>12 try to remember what they read on Page 61 of a</p> <p>13 250-page manual.</p> <p>14 Q. But you don't have any direct</p> <p>15 evidence of that as regards Rachel Dennert?</p> <p>16 A. Yeah, there's no testimony from</p> <p>17 Rachel Dennert regarding that topic.</p> <p>18 Q. Would you agree with me then that</p> <p>19 if Rachel Dennert didn't read it, then there's</p> <p>20 no -- then the failure to have a warning in</p> <p>21 the user guide would not be causally related</p> <p>22 to her incident?</p> <p>23 MR. SKLARSKY: Note an objection to</p> <p>24 the form, but if you understand it, you can</p> <p>25 answer it.</p>
<p style="text-align: right;">Page 309</p> <p>1 W. VIGILANTE</p> <p>2 A. Yeah, as I note in my report, I</p> <p>3 didn't do an analysis of the pump user guide</p> <p>4 and whether or not that section was adequate</p> <p>5 or not, but I can tell you that the pump user</p> <p>6 guide, it's my understanding, is -- is used as</p> <p>7 a -- as part of a training tool during the --</p> <p>8 the education session -- education sessions</p> <p>9 with the patients; and if the instructors</p> <p>10 aren't alerted or warned about it, there's no</p> <p>11 reason for them to know that a problem</p> <p>12 potentially could occur, and, therefore,</p> <p>13 there's no reason for them to provide direct</p> <p>14 warning to the patient when they're in a</p> <p>15 education session. So that -- that's</p> <p>16 certainly problematic.</p> <p>17 And, again, given the severity of</p> <p>18 the consequences, you would expect it would</p> <p>19 have been in the -- in the pump manual too and</p> <p>20 something stressed to the trainers and the</p> <p>21 doctors who are prescribing these things to</p> <p>22 the patients.</p> <p>23 Q. If you -- if the reliance by</p> <p>24 Medtronic on the communication of the pump</p> <p>25 user guide is not reasonable because it's a</p>	<p style="text-align: right;">Page 310</p> <p>1 W. VIGILANTE</p> <p>2 long document, is it your point that Medtronic</p> <p>3 could reasonably expect to rely upon the IFU,</p> <p>4 assuming it provided what you believe would be</p> <p>5 appropriate content --</p> <p>6 MR. SKLARSKY: Just note --</p> <p>7 Q. -- if it did, could they rely on</p> <p>8 it?</p> <p>9 MR. SKLARSKY: I'll just note an</p> <p>10 objection. I'm a little unclear who's</p> <p>11 relying on who here. I'm a little --</p> <p>12 MR. SCHULTZ: Yeah. Let me -- let</p> <p>13 me rephrase it.</p> <p>14 Q. Mr. Vigilante, first of all,</p> <p>15 you've opined that it wouldn't be reasonable</p> <p>16 for Medtronic to rely upon the content of the</p> <p>17 user guide; correct?</p> <p>18 A. Yeah, my opinion is given the</p> <p>19 importance of the reservoir's IFU to the user</p> <p>20 when they are actually connecting the</p> <p>21 reservoir to the infusion set using the P-cap</p> <p>22 connector, Medtronic and Unomedical should</p> <p>23 have ensured -- I'm sorry. I'm giving you the</p> <p>24 wrong -- wrong section of my report.</p> <p>25 My opinion is given the hazard</p>

1 W. VIGILANTE

2 associated with the contamination of the top  
3 of the reservoir -- excuse me, the bottom of  
4 the P-cap vents, the provision of the IFUs for  
5 the infusion sets, the length and bulk of the  
6 user guide and the likelihood of a user  
7 relying upon that at a given infusion set  
8 change after initial training, it was not  
9 reasonable for Unomedical and Medtronic to  
10 rely upon the user guide.

11 MS. MARTINEZ: Object to the answer.  
12 Move to strike.

13 Q. If the content of the instructions  
14 for use of the reservoir were in every way  
15 adequate and appropriate in your opinion,  
16 would Medtronic be reasonable, and for that  
17 matter would Unomedical be reasonable in  
18 relying upon the IFU, assuming its content  
19 were everything you would like it to be?

20 A. Yeah, if they provided adequate  
21 instructions, it would have been the  
22 reasonable thing to do and they would have  
23 ensured the patient, the caregiver, and the  
24 educators were provided with the information  
25 they needed to identify the hazard and how to

1 W. VIGILANTE

2 avoid it.

3 Q. Okay. Earlier you said that  
4 Medtronic -- I think you acknowledged that  
5 Medtronic Certified Diabetes Educator provided  
6 training to Rachel Dennert. Do you recall  
7 that?

8 A. Are you asking if I recall  
9 testifying to that or if I recall that it  
10 happened?

11 Q. Well, do you recall testifying?

12 A. I'm going to say, yes, 'cause we  
13 probably talked about it.

14 Q. Okay. Do you -- to your  
15 knowledge, it did, in fact, happen; correct?

16 A. Yeah, it's my understanding there  
17 was two sessions with the continuing -- or  
18 the -- I have the acronym here somewhere, so  
19 I'm sorry for stumbling on my words, the  
20 Certified Diabeetic -- Diabetic Educator.

21 Q. Okay. Do you have any evidence of  
22 what the Certified Diabetes Educator trained  
23 Rachel Dennert to do with respect to removing  
24 the reservoir from the insulin vial during  
25 that training?

1 W. VIGILANTE

2 A. I don't have any -- anything other  
3 than what Mrs. Nancy Dennert testified to, and  
4 I don't think that that was discussed in any  
5 detail.

6 Q. Okay. Do you have an  
7 understanding -- I just want to make sure I'm  
8 clear.

9 Do you have any understanding  
10 about what Ms. -- Mrs. Dennert, Nancy Dennert,  
11 said with respect to the content of that  
12 training?

13 A. I don't recall all of it, but I --  
14 I don't recall there being any discussion as  
15 to the details regarding this particular step  
16 of the infusion set reservoir connection  
17 process.

18 Q. Okay. As you sit here today, you  
19 don't know what the Certified Diabetes  
20 Educator showed Rachel Dennert to do during  
21 their in-person training sessions; is that  
22 true?

23 A. Yes, yes and no.

24 Q. In what way no?

25 A. Well --

1 W. VIGILANTE

2 Q. In what way do you have evidence  
3 that you know what the Diabetes Educator  
4 trained Rachel Dennert to do during those  
5 in-person training sessions?

6 A. Yeah, I don't know if she  
7 physically showed her how to connect the -- or  
8 fill the reservoir and detach the reservoir  
9 and connect it to the P-cap. I don't know if  
10 she physically showed her that and I don't  
11 know if when she was physically doing that if  
12 she did it correctly, but what I do know is  
13 that when Medtronic finally became aware of  
14 the issue, they had to send out education  
15 packets to their trainers. So it's very  
16 unlikely that the trainer was aware that it  
17 was a necessity to do it in a certain  
18 orientation or that there was a hazard  
19 associated with doing it incorrectly or having  
20 a -- insulin get on the top of the reservoir  
21 before connecting it to the P-cap. So  
22 that's --

23 Q. Do you --

24 A. -- why it's yes and no.

25 Q. I'm sorry. Do you presume that

<p style="text-align: right;">Page 315</p> <p>1 W. VIGILANTE</p> <p>2 the Certified Diabetes Educator showed Rachel</p> <p>3 Dennert the proper way to remove the reservoir</p> <p>4 from the insulin vial?</p> <p>5 A. I don't presume either way.</p> <p>6 Q. Okay. Do you have any evidence</p> <p>7 that Rachel Dennert did not understand what</p> <p>8 she was instructed by the Certified Diabetes</p> <p>9 Educator?</p> <p>10 A. Yeah, I -- since I don't know what</p> <p>11 was done and how it was done, I can't say, but</p> <p>12 I will say that it's my opinion that Rachel</p> <p>13 Dennert did not appreciate the hazard at the</p> <p>14 time she was provided with that training from</p> <p>15 the Certified Diabetes Educator.</p> <p>16 Q. And your opinion in that regard</p> <p>17 comes from -- you take as the starting point</p> <p>18 Mr. Klimowicz's description of how he believes</p> <p>19 the incident occurred, right, that's the</p> <p>20 starting point for that?</p> <p>21 A. Yeah, I don't know if that's the</p> <p>22 starting point for that. I mean, the starting</p> <p>23 point is the fact that Medtronic's own lab</p> <p>24 guys that were trying to figure out how this</p> <p>25 thing occurred couldn't figure out how it</p>	<p style="text-align: right;">Page 316</p> <p>1 W. VIGILANTE</p> <p>2 occurred at first and had to think about what</p> <p>3 was going on for him to end up with the green</p> <p>4 diluent on his -- on his reservoir. So that</p> <p>5 was, you know, Medtronic's own people that</p> <p>6 were very highly experienced in this. It's</p> <p>7 completely doubtful that Rachel Dennert would</p> <p>8 have appreciated it on her own without</p> <p>9 warnings and instructions from Medtronic and</p> <p>10 Unomedical, so I think that's where it starts.</p> <p>11 MS. MARTINEZ: Object to the answer.</p> <p>12 Move to strike.</p> <p>13 A. I was going to say that the hazard</p> <p>14 itself is not open and obvious, there --</p> <p>15 therefore, without adequate instructions and</p> <p>16 warnings, the person is not going to pick it</p> <p>17 up. A regular user is just not going to</p> <p>18 appreciate it or identify it.</p> <p>19 Q. But in what way were the</p> <p>20 instructions given by the Certified Diabetes</p> <p>21 Educator inadequate?</p> <p>22 A. Well, again, I don't know exactly</p> <p>23 what she did and how she did it, but I do know</p> <p>24 that it is highly unlikely that the Certified</p> <p>25 Education -- Diabetes Educator was aware of</p>
<p style="text-align: right;">Page 317</p> <p>1 W. VIGILANTE</p> <p>2 the hazard; and if they're not aware of the</p> <p>3 hazard, how can they inform Rachel Dennert of</p> <p>4 the hazard? And if she doesn't inform her of</p> <p>5 the hazard, then the instructions, by default,</p> <p>6 were inadequate and ineffective.</p> <p>7 Q. Well, whether or not the Certified</p> <p>8 Diabetes Educator informed Ms. Dennert of a</p> <p>9 hazard, as you put it, associated with</p> <p>10 removing the reservoir from the insulin</p> <p>11 bottle, do you have any direct evidence that</p> <p>12 Rachel Dennert didn't do as she was instructed</p> <p>13 by the Diabetes Educator?</p> <p>14 A. If you mean by direct -- again, I</p> <p>15 don't have Rachel Dennert's testimony as to</p> <p>16 exactly what she did. Unfortunately, I</p> <p>17 believe there was some brain damage associated</p> <p>18 with the incident, so you -- probably expect</p> <p>19 you're not going to get it from her, and it</p> <p>20 was never asked of Mrs. -- her mom.</p> <p>21 Q. Are you aware that Mrs. Dennert,</p> <p>22 Nancy Dennert, testified that Rachel Dennert</p> <p>23 followed the instructions that were given to</p> <p>24 her by the Certified Diabetes Educator?</p> <p>25 A. I am aware of that.</p>	<p style="text-align: right;">Page 318</p> <p>1 W. VIGILANTE</p> <p>2 Q. Okay. And are you aware that the</p> <p>3 Certified Diabetes Educator provided Rachel</p> <p>4 Dennert with an instruction sheet during the</p> <p>5 training?</p> <p>6 A. Yes.</p> <p>7 Q. Have you seen that instruction</p> <p>8 sheet?</p> <p>9 A. I have not seen that or I'm not</p> <p>10 aware if that's the same as the IFU provided</p> <p>11 with the reservoir.</p> <p>12 Q. Do you have any information about</p> <p>13 what Rachel Dennert knew or didn't know or</p> <p>14 understood or didn't understand about the</p> <p>15 instruction sheet --</p> <p>16 MR. SKLARSKY: Objection to the --</p> <p>17 Q. -- that was provided to her?</p> <p>18 MR. SKLARSKY: Objection to the</p> <p>19 form, but if you understand it, go ahead.</p> <p>20 A. Yeah, I -- there's no testimony</p> <p>21 from Rachel Dennert on that topic that I'm</p> <p>22 aware of.</p> <p>23 Q. Do you -- Mr. Vigilante, is</p> <p>24 there -- in your field of expertise, is there</p> <p>25 a -- is there a -- a notion, an accepted</p>

<p style="text-align: right;">Page 319</p> <p>1 W. VIGILANTE</p> <p>2 wisdom that hands-on training is more</p> <p>3 effective than printed warnings or</p> <p>4 instructions?</p> <p>5 A. Sure. If you're given training on</p> <p>6 how to use a product and part of that training</p> <p>7 is using written warnings and instructions,</p> <p>8 that's an effective way to do it provided that</p> <p>9 the training itself is -- is adequate. One of</p> <p>10 the issues with training, and why we provide</p> <p>11 printed instructions and warning, is that if</p> <p>12 the training is not repetitive, over time</p> <p>13 people have a tendency to forget what they</p> <p>14 learned in that training, so somehow or</p> <p>15 another the training has to be reinforced; and</p> <p>16 that's where the warnings and instructions</p> <p>17 come into play.</p> <p>18 MR. SCHULTZ: Madame Court Reporter,</p> <p>19 would you mark the exhibit labeled</p> <p>20 Instructional CDROM.</p> <p>21 (Exhibit Vigilante-19, CDROM</p> <p>22 entitled Rachel Dennert vs. Medtronic</p> <p>23 Instructional CD-ROM MDT071234RD, is marked</p> <p>24 for identification.)</p> <p>25 Q. Mr. Vigilante, the court reporter</p>	<p style="text-align: right;">Page 320</p> <p>1 W. VIGILANTE</p> <p>2 has handed you what's been marked as</p> <p>3 Exhibit 19, which is an instructional video or</p> <p>4 an instructional CDROM. I'm not going to make</p> <p>5 you look at it now, but I'll represent to you</p> <p>6 that this is the -- a copy of the video that</p> <p>7 is shipped with the pump to -- the pump that</p> <p>8 was shipped to Rachel Dennert.</p> <p>9 With that description, have you</p> <p>10 seen such a video before?</p> <p>11 A. I have seen a video from</p> <p>12 Medtronic. I don't know if it's the same</p> <p>13 video that's on the -- on the -- the CD or</p> <p>14 not.</p> <p>15 Q. Okay. Did the video you've seen</p> <p>16 from Medtronic show the process of filling the</p> <p>17 reservoir and removing it from the insulin</p> <p>18 vial?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. What did it depict that you</p> <p>21 recall?</p> <p>22 A. Well, I can open it up.</p> <p>23 (Opening file on computer).</p> <p>24 One of the versions I have is a --</p> <p>25 not alive actors, it's a -- a --</p>
<p style="text-align: right;">Page 321</p> <p>1 W. VIGILANTE</p> <p>2 Q. I didn't hear. I'm sorry.</p> <p>3 A. It's an animation of -- the</p> <p>4 version I have is an animation.</p> <p>5 Q. Okay. Well, let's do it this way.</p> <p>6 Are you aware that a video such as</p> <p>7 Exhibit 19 is physically shipped with the pump</p> <p>8 to pump users?</p> <p>9 A. Yeah, I don't recall. The only</p> <p>10 thing I recall with respect to videos is that</p> <p>11 Nancy Dennert testified that Rachel watched</p> <p>12 the videos provided, but there -- I don't</p> <p>13 remember any testimony as to where those</p> <p>14 videos came from, if they came from a CD with</p> <p>15 the pump or they were a part of the online</p> <p>16 education. I don't -- I don't recall.</p> <p>17 Q. Okay. So in terms of whether</p> <p>18 Rachel Dennert reviewed the particular video</p> <p>19 that is Exhibit 19, you don't know</p> <p>20 specifically, but Mrs. Dennert testified that</p> <p>21 she reviewed the video she was provided; is</p> <p>22 that true?</p> <p>23 A. Well, no. The way I'd be more</p> <p>24 comfortable saying it is I don't know if she</p> <p>25 received or reviewed a CD that accompanied a</p>	<p style="text-align: right;">Page 322</p> <p>1 W. VIGILANTE</p> <p>2 pump or if she reviewed videos that were</p> <p>3 online. I don't know at this point.</p> <p>4 Q. Okay. If she did receive it, do</p> <p>5 you know whether she reviewed it?</p> <p>6 MR. SKLARSKY: Well, objection to</p> <p>7 the form, you know, if he doesn't know</p> <p>8 specifically what -- what -- what was</p> <p>9 received.</p> <p>10 A. Yeah, I don't know. I don't know</p> <p>11 if she received it or if she reviewed this</p> <p>12 particular CD or not.</p> <p>13 Q. Okay. So then it's a fair</p> <p>14 statement that you don't have any information</p> <p>15 as to whether she viewed Exhibit 19; and if</p> <p>16 she viewed it, whether she understood it or</p> <p>17 not?</p> <p>18 A. Yeah, I don't have any testimony</p> <p>19 regarding that.</p> <p>20 Q. All right. In terms of any</p> <p>21 additional, for example, online-pump training,</p> <p>22 do you know what, if anything, Rachel Dennert</p> <p>23 viewed or didn't view?</p> <p>24 A. I -- again, according to -- to her</p> <p>25 mom, Rachel went through the Medtronic pump</p>

<p style="text-align: right;">Page 323</p> <p>1 W. VIGILANTE</p> <p>2 school online. That -- that's what I have</p> <p>3 noted in my report.</p> <p>4 Q. Okay. But in terms of what's</p> <p>5 there, you don't know as you sit here today?</p> <p>6 MR. SKLARSKY: When you say what --</p> <p>7 what --</p> <p>8 Q. In terms of the content of that</p> <p>9 online-pump training, that she may or may not</p> <p>10 have viewed, you don't know the content of it;</p> <p>11 right?</p> <p>12 A. Well, I thought I had the content</p> <p>13 of it in these videos, but, again, I -- it</p> <p>14 could be very well that that content came from</p> <p>15 the disk. I don't know at this point.</p> <p>16 Q. Okay. Okay.</p> <p>17 MR. SCHULTZ: Can you -- Madame</p> <p>18 Court Reporter, can you mark as Exhibit 20</p> <p>19 the help -- Self-Help Storyboard Filling</p> <p>20 the Reservoir.</p> <p>21 (Exhibit Vigilante-20, multipage</p> <p>22 document entitled Self-Help Storyboard</p> <p>23 Filling the Reservoir and Priming bearing</p> <p>24 Bates Numbers MDT071290RD through</p> <p>25 MDT071322RD, is marked for identification.)</p>	<p style="text-align: right;">Page 324</p> <p>1 W. VIGILANTE</p> <p>2 THE WITNESS: Thank you.</p> <p>3 MR. SKLARSKY: What number is that?</p> <p>4 COURT REPORTER: 20.</p> <p>5 Q. Mr. Vigilante, the court reporter</p> <p>6 has handed you Exhibit Number 20.</p> <p>7 A. Yes.</p> <p>8 Q. Have you seen that exhibit before</p> <p>9 today?</p> <p>10 A. I have not.</p> <p>11 Q. All right. Do you know whether or</p> <p>12 not this storyboard on filling the reservoir</p> <p>13 is part of the online-pump training?</p> <p>14 A. I do not know.</p> <p>15 Q. All right. Do you know whether or</p> <p>16 not Rachel Dennert reviewed it?</p> <p>17 A. I do not.</p> <p>18 Q. Okay. All right. Well, let's go</p> <p>19 back to the IFU itself. If you --</p> <p>20 MR. SCHULTZ: Madame Court Reporter,</p> <p>21 would you hand Mr. Vigilante the previously</p> <p>22 marked Exhibit 17, the reservoir IFU.</p> <p>23 (Exhibit Vigilante-17, document</p> <p>24 entitled Medtronic MiniMed Paradigm</p> <p>25 Reservoir Rx Only, was previously marked</p>
<p style="text-align: right;">Page 325</p> <p>1 W. VIGILANTE</p> <p>2 for identification.)</p> <p>3 THE WITNESS: Thank you.</p> <p>4 COURT REPORTER: He has it.</p> <p>5 MR. SCHULTZ: Oh, thank you.</p> <p>6 Q. Mr. Vigilante, I want to make sure</p> <p>7 that I have all of your critiques of this</p> <p>8 document in mind.</p> <p>9 First of all, you're looking at</p> <p>10 Exhibit 6 -- or 17, which is the IFU, the</p> <p>11 actual IFU that was shipped with Rachel</p> <p>12 Dennert's reservoirs; is that correct?</p> <p>13 A. I don't recall which one was</p> <p>14 marked in the last deposition as the one that</p> <p>15 Mr. Haverty provided or the one that you</p> <p>16 provided, so I -- I don't recall.</p> <p>17 Q. Okay. Do you happen to have the</p> <p>18 one that Mr. Haverty provided, the -- the one</p> <p>19 that was actually shipped --</p> <p>20 A. I'm sor --</p> <p>21 Q. -- the actual piece of paper?</p> <p>22 A. I'm sorry. I do not.</p> <p>23 MR. SKLARSKY: Dave --</p> <p>24 Q. Oh, okay.</p> <p>25 MR. SKLARSKY: Dave, could I just</p>	<p style="text-align: right;">Page 326</p> <p>1 W. VIGILANTE</p> <p>2 ask because I noticed that there were, and</p> <p>3 I don't recall exactly what the testimony</p> <p>4 was about them, but there was an Exhibit 15</p> <p>5 and 17.</p> <p>6 MR. SCHULTZ: Yeah, and I -- and I'm</p> <p>7 pretty sure that 17 was the one that</p> <p>8 Mr. Haverty provided.</p> <p>9 MR. SKLARSKY: Okay.</p> <p>10 MR. SCHULTZ: And, frankly, I think</p> <p>11 15 and 17 have the exact same content</p> <p>12 but...</p> <p>13 MR. SKLARSKY: If they're identical,</p> <p>14 then then I guess it won't matter, you</p> <p>15 know, which one we use but...</p> <p>16 MR. SCHULTZ: Yeah, but I'll just</p> <p>17 ask him about 17.</p> <p>18 BY MR. SCHULTZ:</p> <p>19 Q. Mr. Vigilante, looking at</p> <p>20 Exhibit 17, your criticism -- first of all,</p> <p>21 Step 6 is the step that depicts removal of the</p> <p>22 reservoir from the insulin vial; correct?</p> <p>23 A. Yes.</p> <p>24 Q. And in the pictograph itself,</p> <p>25 would you agree that it displays the reservoir</p>

<p style="text-align: right;">Page 327</p> <p>1 W. VIGILANTE</p> <p>2 being removed from the transfer guard with the</p> <p>3 reservoir above the vial; correct?</p> <p>4 A. Yes. I'm sorry. Yes.</p> <p>5 Q. And the pictograph itself is not</p> <p>6 hard to distinguish. I mean, you can -- you</p> <p>7 can look at it --</p> <p>8 (Reporter clarification.)</p> <p>9 MR. SCHULTZ: I'm sorry. Let --</p> <p>10 I'll start it over.</p> <p>11 Q. Would you agree, Mr. Vigilante,</p> <p>12 that the pictograph itself -- in the</p> <p>13 pictograph itself it's not hard to distinguish</p> <p>14 what is the reservoir from what is the</p> <p>15 transfer guard from what is the vial? Would</p> <p>16 you agree with that?</p> <p>17 A. I can tell what it is.</p> <p>18 Q. Okay. Among the criticisms you've</p> <p>19 made about this are, number one, it doesn't --</p> <p>20 the IFU doesn't say, "Make sure to remove the</p> <p>21 reservoir from the transfer guard with the</p> <p>22 reservoir above the vial," correct? That's</p> <p>23 one of your criticisms?</p> <p>24 A. Yeah, there's no text with the</p> <p>25 step.</p>	<p style="text-align: right;">Page 328</p> <p>1 W. VIGILANTE</p> <p>2 Q. Okay. And it doesn't warn the</p> <p>3 user that if you go through -- if -- if</p> <p>4 certain things happen with liquid being</p> <p>5 deposited on the top of the reservoir and then</p> <p>6 transferred to the underside of the P-cap, it</p> <p>7 doesn't contain any warnings about that;</p> <p>8 correct?</p> <p>9 A. Yeah, there is no warning</p> <p>10 regarding the particular hazard.</p> <p>11 Q. Okay. Is there other -- any other</p> <p>12 way in which -- I want to make sure I have all</p> <p>13 your criticisms. Are there other things about</p> <p>14 the IFU's communication to the user about</p> <p>15 removal of the reservoir from the insulin vial</p> <p>16 that you think is deficient?</p> <p>17 A. Well, it's laid out in my report,</p> <p>18 but there are multiple things. So, one --</p> <p>19 Q. Well, just --</p> <p>20 A. -- particular to Step 6, there's</p> <p>21 no accompanied sub-step that shows the actual</p> <p>22 flip; and of course that's important because</p> <p>23 in Step 5 the vial and the reservoir are</p> <p>24 inverted. So there was a flip between Step 5</p> <p>25 and Step 6, but that actively flipping it is</p>
<p style="text-align: right;">Page 329</p> <p>1 W. VIGILANTE</p> <p>2 not depicted anywhere and it's not highlighted</p> <p>3 or stressed in Step 6 that it was flipped.</p> <p>4 And then, again, on Step 7 the reservoir is</p> <p>5 flipped again. So the fact that the IFU is</p> <p>6 showing multiple orientation changes, but not</p> <p>7 calling it out is a criticism that I have with</p> <p>8 the IFU as well.</p> <p>9 Additional criticism I have is,</p> <p>10 again, the step depicted in 6 is unnatural and</p> <p>11 contrary to traditional norms. So you're</p> <p>12 asking somebody to do something that they</p> <p>13 normally wouldn't do naturally and, again,</p> <p>14 there's no instruction or warning to let folks</p> <p>15 know that that's what the -- that's what's</p> <p>16 required.</p> <p>17 Q. Any others? I just want to make</p> <p>18 sure that I have them all, and I -- I know</p> <p>19 they're in your report, but I just want to</p> <p>20 make sure I have them.</p> <p>21 A. They're the ones that come to mind</p> <p>22 at the moment. I mean, we --</p> <p>23 Q. Okay.</p> <p>24 A. -- we've been through this in the</p> <p>25 last deposition. We went through it in my</p>	<p style="text-align: right;">Page 330</p> <p>1 W. VIGILANTE</p> <p>2 report.</p> <p>3 Q. Okay. Is -- and do you have</p> <p>4 evidence, is it your understanding that Rachel</p> <p>5 Dennert read this IFU?</p> <p>6 A. That's my understanding.</p> <p>7 Q. Okay. And that's based on the</p> <p>8 testimony of Nancy Dennert; correct?</p> <p>9 A. Yes, and the fact that the -- this</p> <p>10 was actually the IFU in the packet of infusion</p> <p>11 sets that she was using.</p> <p>12 Q. Okay. Do you have any evidence,</p> <p>13 any testimony that Rachel Dennert read it more</p> <p>14 than once?</p> <p>15 A. I think Nancy said -- her mom</p> <p>16 testified that she used it when she connected</p> <p>17 it. So my understanding was that she did read</p> <p>18 it and use it more than once.</p> <p>19 Q. Well, do you understand actually</p> <p>20 that Nancy Dennert testified that -- I think</p> <p>21 the testimony, and if I've got it wrong, I've</p> <p>22 got it wrong, but that Nancy Dennert testified</p> <p>23 that Rachel Dennert followed the instruction</p> <p>24 sheet she was given at the time she</p> <p>25 connected -- or filled the reservoir and</p>

1 W. VIGILANTE  
2 connected it on August 8th of 2009?  
3 A. I'm -- I'm sorry. I'm going to  
4 have to look in my report where I have it  
5 noted.  
6 Q. Sure.  
7 MR. SKLARSKY: Page 6.  
8 A. Yeah, I'm -- in her deposition  
9 Pages 203 to 205 Nancy testified that Rachel  
10 used and followed the directions whenever she  
11 performed those tasks, and that was a -- a  
12 printout of instructions.  
13 Q. Okay. And a printout of  
14 instructions, do you understand it to be the  
15 IFU?  
16 A. That's my understanding.  
17 Q. Okay. Do you -- well -- okay.  
18 Do you have any evidence that she,  
19 she Rachel Dennert, if she was using the IFU  
20 as opposed to printed instructions given to  
21 her by the Certified Diabetes Educator, that  
22 she didn't understand how to follow the IFU?  
23 A. One more time.  
24 Q. Yeah. Sorry. Do you have any  
25 evidence that she, Rachel Dennert, didn't

1 W. VIGILANTE  
2 understand how to follow the IFU?  
3 A. Yeah, so that's a -- kind of a --  
4 a fuzzy question. So my understanding is, is  
5 that she was able to successfully -- what she  
6 thought successfully connect the infusion set  
7 to a filled reservoir. Whether she properly,  
8 that is doing everything to a T as depicted in  
9 the IFU, there is no testimony that she did,  
10 but the evidence is based upon the failure of  
11 the IFU and the other evidence in the case,  
12 and the YouTube videos, it's likely that she  
13 wasn't.  
14 Q. All right. Let me break it down.  
15 No one testified that Rachel  
16 Dennert didn't understand the IFU; right?  
17 A. That's correct.  
18 Q. And no one testified that Rachel  
19 Dennert didn't follow exactly what the IFU  
20 instructed; correct?  
21 A. Well, that's not correct.  
22 Q. Okay. What testimony is there  
23 that she did not follow what the IFU  
24 instructed?  
25 A. Well, Nancy testified at the

1 W. VIGILANTE  
2 six o'clock changing that Rachel reported the  
3 insulin spilling out, which is consistent with  
4 doing it with the insulin vial over the  
5 reservoir. I'm not sure how the insulin gets  
6 out otherwise, both the insulin and the  
7 reservoir are sealed units and they're  
8 punctured by the transfer guard, so I don't  
9 know how the insulin gets out otherwise.  
10 Q. Is it your understanding that  
11 Nancy Dennert testified -- well, first of all,  
12 the six o'clock set change is not the one at  
13 issue in this lawsuit; right? It's not the  
14 one that supposedly injured Rachel Dennert.  
15 A. The one that is involved with the  
16 prime fill anomaly, my understanding from  
17 Dr. Kilowitz [sic], was the eleven o'clock  
18 changeover.  
19 Q. Okay. And is it your  
20 understanding that Nancy Dennert testified  
21 that insulin was spilling out of the infusion  
22 set at the six o'clock change?  
23 A. My understanding is that Rachel  
24 told Nancy that insulin had spilled when she  
25 was doing the change at six o'clock.

1 W. VIGILANTE  
2 Q. Okay. But you have no other  
3 details about how the insulin spilled at the  
4 six o'clock change; correct?  
5 A. No, Nancy was not there to witness  
6 it.  
7 Q. Okay. And Rachel hasn't testified  
8 in any greater detail about that either;  
9 correct?  
10 A. Not that I'm aware of.  
11 Q. Okay.  
12 A. You guys want --  
13 Q. And in terms of the --  
14 A. -- to take a break? We've been --  
15 MR. SKLARSKY: Dave --  
16 MR. SCHULTZ: I'm sorry.  
17 MR. SKLARSKY: Dave, could we take a  
18 short break at this point?  
19 MR. SCHULTZ: Sure.  
20 THE WITNESS: Yep, thank you.  
21 THE VIDEOGRAPHER: We are now going  
22 off the video record. That concludes DVD  
23 Number 1. The time is 11:43.  
24 (A recess is held from 11:42 a.m. to  
25 12:01 p.m.)

<p style="text-align: right;">Page 335</p> <p>1 W. VIGILANTE</p> <p>2 THE VIDEOGRAPHER: We are now back</p> <p>3 on the video record. This commences DVD</p> <p>4 Number 2. The date, September 23rd, 2016.</p> <p>5 The time, 12:01.</p> <p>6 BY MR. SCHULTZ:</p> <p>7 Q. Mr. Vigilante, just a couple of</p> <p>8 more questions on this -- on the topic we were</p> <p>9 on before we took a break.</p> <p>10 Regarding, excuse me, Rachel</p> <p>11 Dennert's use of the IFU for the reservoir at</p> <p>12 the time of her incident, no one -- am I</p> <p>13 correct that no one has testified that Rachel</p> <p>14 Dennert did not -- let me back up. Let me</p> <p>15 rephrase that.</p> <p>16 No one has testified, to your</p> <p>17 knowledge, that Rachel Dennert forgot what was</p> <p>18 in the IFU at the time she filled the</p> <p>19 reservoir on the evening of August 8th, 2009;</p> <p>20 correct?</p> <p>21 A. One more time.</p> <p>22 Q. Yeah. I'm sorry. Nobody has</p> <p>23 testified that Rachel Dennert forgot what she</p> <p>24 was instructed by the IFU; correct?</p> <p>25 A. Yeah, there's no testimony that</p>	<p style="text-align: right;">Page 336</p> <p>1 W. VIGILANTE</p> <p>2 she forgot.</p> <p>3 Q. And there's no testimony that she</p> <p>4 made a deliberate decision not to follow the</p> <p>5 instructions in the IFU?</p> <p>6 A. That's my understanding.</p> <p>7 Q. And there's no testimony that</p> <p>8 anybody saw her fill the reservoir in a manner</p> <p>9 that was inconsistent with the IFU?</p> <p>10 A. There's no testimony either way.</p> <p>11 Q. All right. Let's talk about the</p> <p>12 warning. Is -- have you drafted or do you</p> <p>13 have language that you believe should have</p> <p>14 been in a warning?</p> <p>15 A. I do on Page -- Page 21 of my</p> <p>16 report of -- let me give you the -- my first</p> <p>17 report, April 19th, 2016.</p> <p>18 Q. Okay. Hang on a second. Let me</p> <p>19 grab that. Page 21, did you say?</p> <p>20 A. Correct.</p> <p>21 Q. Is that -- I see it. "A warning</p> <p>22 should have accompanied Step 7a which stated,"</p> <p>23 and then you have the language; correct?"</p> <p>24 A. Yes.</p> <p>25 Q. Is that, in your view, essentially</p>
<p style="text-align: right;">Page 337</p> <p>1 W. VIGILANTE</p> <p>2 the same as the content of what was contained</p> <p>3 in the 2013 healthcare advisory to doctors?</p> <p>4 Have you seen that?</p> <p>5 A. Yes, I have seen that.</p> <p>6 Q. And is this essentially the same</p> <p>7 in your mind?</p> <p>8 A. I'm looking to see if that's where</p> <p>9 I got the language from or if I obtained it</p> <p>10 from somewhere else.</p> <p>11 The information in my warning is</p> <p>12 similar to the warning -- or the information</p> <p>13 provided in the -- the letter sent to the</p> <p>14 healthcare providers on June 7th, 2013.</p> <p>15 Q. Okay. And let me just ask that a</p> <p>16 different way. Since you've reviewed that</p> <p>17 information in the June 7th, 2013 letter,</p> <p>18 would you agree that that was a -- an adequate</p> <p>19 warning as it were?</p> <p>20 A. The June -- June 7th, 2013?</p> <p>21 Q. Yeah.</p> <p>22 A. It provides information to the</p> <p>23 healthcare provider. I didn't assess whether</p> <p>24 or not it was adequate or not. The</p> <p>25 information --</p>	<p style="text-align: right;">Page 338</p> <p>1 W. VIGILANTE</p> <p>2 Q. Are -- are --</p> <p>3 A. -- that was necessary was in</p> <p>4 there.</p> <p>5 Q. Okay. Are you aware that this</p> <p>6 letter in substance was provided to patients</p> <p>7 as well --</p> <p>8 A. Well, this --</p> <p>9 Q. -- at that time?</p> <p>10 A. -- this particular letter wasn't.</p> <p>11 There was another letter that was sent to</p> <p>12 patients.</p> <p>13 Q. Right. At or around the same</p> <p>14 time; correct?</p> <p>15 A. Yeah, I don't have the dates</p> <p>16 offhand, but that's my understanding.</p> <p>17 Q. Yeah, containing the same or</p> <p>18 similar information about keeping the</p> <p>19 reservoir top and tube connector clean and</p> <p>20 dry?</p> <p>21 A. Yeah, I don't have the letter</p> <p>22 pulled up, but from my memory it contains</p> <p>23 similar information.</p> <p>24 Q. Okay. In your opinion, this</p> <p>25 warning or something like what you have in the</p>

<p style="text-align: right;">Page 339</p> <p>1 W. VIGILANTE</p> <p>2 report should be included in the IFU for the</p> <p>3 reservoir; correct?</p> <p>4 A. It should have been, yes.</p> <p>5 Q. And would you agree that whether</p> <p>6 or not such a warning were included, if Rachel</p> <p>7 Dennert followed the instructions about how to</p> <p>8 fill the reservoir and disconnect from the</p> <p>9 transfer guard, then the absence of warning</p> <p>10 isn't causally related to her injury?</p> <p>11 MR. SKLARSKY: Well, can -- can you</p> <p>12 read back that question?</p> <p>13 (The following portion of the record</p> <p>14 is read by the Court Reporter:</p> <p>15 "QUESTION: And would you agree that</p> <p>16 whether or not such a warning were</p> <p>17 included, Rachel -- if Rachel Dennert</p> <p>18 followed the instructions about -- about</p> <p>19 how to fill the reservoir and disconnect</p> <p>20 from the transfer guard, then the absence</p> <p>21 of warning isn't causally related to her</p> <p>22 injury?")</p> <p>23 MR. SKLARSKY: Just note an</p> <p>24 objection and maybe just -- I'm just having</p> <p>25 some confusion with how it's phrased, but</p>	<p style="text-align: right;">Page 340</p> <p>1 W. VIGILANTE</p> <p>2 if he understands it, he can answer it.</p> <p>3 A. Yeah, I'm sorry. I don't</p> <p>4 understand it.</p> <p>5 MR. SCHULTZ: All right. Let me</p> <p>6 see if I can rephrase it.</p> <p>7 Q. If Rachel Dennert, in fact,</p> <p>8 followed the instructions and removed the</p> <p>9 reservoir from above the insulin vial on</p> <p>10 August 8th, 2009, then would you agree that</p> <p>11 the presence or absence of a warning would not</p> <p>12 be causally related to her injury?</p> <p>13 A. So if I can rephrase the question,</p> <p>14 maybe I can understand it a little better</p> <p>15 because it's a little ambiguous. If she had</p> <p>16 removed the reservoir from the transfer guard</p> <p>17 with the insulin vial held below the reservoir</p> <p>18 as depicted in Step 6, is that essentially</p> <p>19 your question?</p> <p>20 Q. Yeah.</p> <p>21 A. Yeah, so, no, I wouldn't agree</p> <p>22 with that because either the contaminant got</p> <p>23 on the -- on the underside of the -- the P-cap</p> <p>24 connector from the insulin from the vial or</p> <p>25 some other method. So the warning was</p>
<p style="text-align: right;">Page 341</p> <p>1 W. VIGILANTE</p> <p>2 necessary to allow -- to alert her that any</p> <p>3 liquid, whether it's insulin or any other</p> <p>4 contaminant, needed to be removed and could be</p> <p>5 a problem.</p> <p>6 Q. Do you have any evidence or are</p> <p>7 you aware of any way in which insulin from the</p> <p>8 vial can get on top of the reservoir if the</p> <p>9 reservoir is removed from the vial from above</p> <p>10 the insulin vial?</p> <p>11 A. Yeah, it's my understanding that</p> <p>12 if the insulin vial is held upright and the</p> <p>13 reservoir is removed from the transfer guard</p> <p>14 inverted above the insulin vial, that the</p> <p>15 insulin will not squirt out of the -- out of</p> <p>16 the vial.</p> <p>17 Q. Okay. Do you know of any evidence</p> <p>18 of a contaminant, some other contaminant</p> <p>19 getting on top of Rachel Dennert's reservoir</p> <p>20 at the time of the incident?</p> <p>21 A. Well, yeah, I don't know if it was</p> <p>22 the insulin or another contaminant, but based</p> <p>23 upon Dr. Klimowicz's analysis, some</p> <p>24 contaminant got on there. So I, you know, I</p> <p>25 don't know for sure whether it was the insulin</p>	<p style="text-align: right;">Page 342</p> <p>1 W. VIGILANTE</p> <p>2 or -- or some other -- other contaminant,</p> <p>3 but --</p> <p>4 Q. But it --</p> <p>5 A. -- it's more likely than not it</p> <p>6 was the insulin from incorrectly removing the</p> <p>7 reservoir from the transfer guard with the</p> <p>8 insulin vial held over the transfer guard as</p> <p>9 you would expect a significant portion of the</p> <p>10 user population would do.</p> <p>11 Q. Mr. Vigilante, let me ask it this</p> <p>12 way.</p> <p>13 Other than Mr. Klimowicz's</p> <p>14 opinion -- well, and, actually, let me back</p> <p>15 up.</p> <p>16 Mr. Klimowicz does not, in fact,</p> <p>17 opine that there was some other contaminant;</p> <p>18 correct?</p> <p>19 A. I think he narrowed it down to the</p> <p>20 insulin.</p> <p>21 Q. Okay. And other than what</p> <p>22 Mr. Klimowicz has said in his report and</p> <p>23 deposition, you're not aware of any evidence</p> <p>24 that there was some other contaminant on the</p> <p>25 top of Rachel Dennert's reservoir at the time</p>

<p style="text-align: right;">Page 343</p> <p>1 W. VIGILANTE</p> <p>2 of the incident; correct?</p> <p>3 A. Yeah, I -- again, I don't know</p> <p>4 whether it was insulin or some other</p> <p>5 contaminant. It -- according to</p> <p>6 Dr. Klimowicz, his assessment it was insulin,</p> <p>7 but given the other evidence in the case, it's</p> <p>8 more likely than not that it was insulin.</p> <p>9 That -- that's the best --</p> <p>10 Q. I didn't hear --</p> <p>11 A. -- I can do for you.</p> <p>12 Q. -- the last part of that. I'm</p> <p>13 sorry.</p> <p>14 MS. MARTINEZ: Yeah, I didn't</p> <p>15 either.</p> <p>16 COURT REPORTER: I'm sorry?</p> <p>17 A. I said it was likely it was</p> <p>18 insulin, but, you know, I can't rule out that</p> <p>19 it was anything else to 100 percent</p> <p>20 probability, but more than likely than not it</p> <p>21 was insulin.</p> <p>22 Q. Is there a concept in your</p> <p>23 discipline of something called, lack of a</p> <p>24 better word, general warning or a gen --</p> <p>25 let me back up.</p>	<p style="text-align: right;">Page 344</p> <p>1 W. VIGILANTE</p> <p>2 For example, if there were a</p> <p>3 warning that said, "Always do this," for</p> <p>4 example, "always check your blood glucose</p> <p>5 after changing your reservoir," would that</p> <p>6 kind of a warning break the causal connection,</p> <p>7 if there is one, between the absence of a</p> <p>8 warning to keep the vents dry and the injury?</p> <p>9 MR. SKLARSKY: I'm going to --</p> <p>10 Q. Do you understand --</p> <p>11 MR. SKLARSKY: I'm going to --</p> <p>12 Q. -- what I've asked?</p> <p>13 MR. SKLARSKY: I'm going to object</p> <p>14 to the question. Only -- maybe I'm wrong.</p> <p>15 It just sounds like to be way out of his</p> <p>16 area of expertise or what he's being</p> <p>17 offered on, unless I'm not understanding</p> <p>18 the question correctly, which I am having a</p> <p>19 little bit of trouble with.</p> <p>20 MR. SCHULTZ: Let me just try and</p> <p>21 rephrase it.</p> <p>22 Q. Is there such a concept as a --</p> <p>23 sort of a general warning?</p> <p>24 A. I'm not sure what you're asking me</p> <p>25 about.</p>
<p style="text-align: right;">Page 345</p> <p>1 W. VIGILANTE</p> <p>2 Q. Okay. Are there, in your</p> <p>3 experience, warnings that are specific to a</p> <p>4 particular failure mode and then warnings that</p> <p>5 are more generally directed at a variety of</p> <p>6 failure modes that would all result in the</p> <p>7 same injury?</p> <p>8 Does that make sense?</p> <p>9 MR. SKLARSKY: Yeah, again, not --</p> <p>10 note an objection. I just -- it's -- at</p> <p>11 least I just don't understand exactly what</p> <p>12 that question is, but if you do...</p> <p>13 A. Yeah, I -- I'm not -- I'm not a</p> <p>14 hundred percent sure. I can tell you that</p> <p>15 effective warnings provide specific and</p> <p>16 explicit information regarding a specific</p> <p>17 hazard. That's -- you know, I think that's --</p> <p>18 that may be the answer to your question. I'm</p> <p>19 not sure.</p> <p>20 Q. All right. How do you define</p> <p>21 "hazard" in this circumstance?</p> <p>22 Is the hazard a temporarily</p> <p>23 blocked vent or is the hazard over-infusion of</p> <p>24 insulin causing low blood sugar?</p> <p>25 A. What was the fir -- what was the</p>	<p style="text-align: right;">Page 346</p> <p>1 W. VIGILANTE</p> <p>2 first part?</p> <p>3 Q. Well, how do you define the</p> <p>4 "hazard" in this case?</p> <p>5 Is it moisture on top of the</p> <p>6 reservoir or is it the potential for low blood</p> <p>7 sugar if there is an over-delivery of insulin?</p> <p>8 A. I think the -- the hazard is the</p> <p>9 prime fill anomaly, that the -- the fact that</p> <p>10 if the vents are blocked, you can have over-</p> <p>11 or under-delivery of insulin. So that's --</p> <p>12 that's the hazard.</p> <p>13 Q. So if there's a warning about how</p> <p>14 to avoid the consequence of low or high blood</p> <p>15 sugar due to some misdelivery of insulin, does</p> <p>16 it matter that there's no warning of the</p> <p>17 particular ways in which that might occur?</p> <p>18 A. Yeah, I'm not quite sure I'm</p> <p>19 understanding, but if I'm -- if I'm -- I think</p> <p>20 you're -- you're going to have to redo the</p> <p>21 question. I'm sorry.</p> <p>22 Q. Okay. Well, let me try it one</p> <p>23 more time.</p> <p>24 If there's a warning that tells</p> <p>25 the user how to avoid either high or low blood</p>

W. VIGILANTE

sugar because of a potential for, you know, an improper delivery of insulin, does it matter that there's not a warning about the different ways in which that might come about? Does that make sense? Do you follow that?

A. I'm trying to. So if there was multiple ways that you can have over- or under-delivery of insulin and each had its own mechanism and each had its own rectification, you would want to provide warning as to what those mechanisms are and how to ensure that they don't occur.

Q. Well, let me give you an example.

If one -- one could receive under-delivery of insulin because the cannula in the patient is bent, one could also receive under-delivery of insulin because the cannula has pulled out, and one could also receive an under-delivery of insulin because the tubing itself in the infusion set gets kinked somehow. If the user is provided with a warning that says, "Make sure to check your blood sugar every so often in case you're not getting enough insulin," does that -- doesn't

W. VIGILANTE

that adequately warn of the consequences of all three ways in which in my hypothetical a user could have an under-delivery of insulin?

A. No.

Q. Why not?

A. Well, there are three different mechanisms that you want to alert the user to the potential of. Those three, you know, tend to be more open and obvious as to the consequences or that there would be consequences as opposed to a prime fill anomaly where it's not open and obvious that there is a consequence, a negative consequence if -- if you take the vial -- if you remove the reservoir from under the vial and you get a contaminant, insulin, et cetera, on the back underside of the P-cap.

So they're two different degrees of mechanisms, but you'd want to alert the user to all of them and how to avoid them, how to identify and how to avoid them. I think your general warning is to, you know, check your blood-glucose level periodically. If that's the right thing to do, that's okay.

W. VIGILANTE

But if it's not associated with a -- a particular mechanism, it doesn't do you any good.

So, for example, if you check your blood -- blood-glucose level at 10:30, see you're a little bit low, and you change out your infusion set and you suffer the prime fill anomaly but you go to bed, you know, you can't get up in the middle of night and -- and check it before all that insulin is dumped into your body. So you want to prevent the insulin from being dumped into your body. You don't want to catch it when you happen to wake up at two o'clock or three o'clock or four o'clock.

So you're -- you're dealing with two different -- two different issues.

Q. What if in your hypothetical the user were warned "Don't change your infusion set before going to bed unless you can stay up and check your blood sugar one -- one, two, three hours after you've changed it," would that be enough?

A. It depends. I'd like to see the

W. VIGILANTE

warning.

Q. All right. Let's turn to your supplemental report, Exhibit, I believe, 11.

In the report you reference -- excuse me -- a number of YouTube videos which are identified in the appendix that comprises Pages 4 and 5; correct?

A. Yes.

Q. Are you aware that as of today a number of the videos that you've referenced in your appendix are not available or don't exist anymore on the -- on the Internet?

A. I'm not aware that they're not.

Q. Okay. Do you know anything -- well, you don't know any of the people yourself who posted these videos; correct?

A. I do not personally know them.

Q. And you don't know what any of the people who posted these videos were trained, when and if they were trained, regarding filling a reservoir; correct?

A. I don't know their exact training that they were exposed to.

Q. Okay. You don't know whether any

<p style="text-align: right;">Page 351</p> <p>1 W. VIGILANTE</p> <p>2 of these people did or didn't read any of the</p> <p>3 materials such as the pump user guide or the</p> <p>4 instructions for use or anything of that</p> <p>5 nature; correct?</p> <p>6 A. I don't recall if any of them had</p> <p>7 the IFU or the pump user guide out at the time</p> <p>8 they were doing it, so I don't know if they --</p> <p>9 if -- I don't recall offhand if they did or</p> <p>10 didn't have the IFU out or pump user manual</p> <p>11 out at the time.</p> <p>12 Q. Is this -- have you ever in any</p> <p>13 opinion in any litigation engagement relied</p> <p>14 upon YouTube videos other than this case?</p> <p>15 A. Yes. It's quite common for</p> <p>16 experts to surf, Google search for</p> <p>17 product-related issues from users of the</p> <p>18 products. It's a good way to -- to gather</p> <p>19 information. Product manufacturers use it as</p> <p>20 well to gather information on how people are</p> <p>21 using their products. It's, you know, used</p> <p>22 from a marketing perspective. It's used from</p> <p>23 a product design perspective.</p> <p>24 Q. I want to --</p> <p>25 A. So it's quite --</p>	<p style="text-align: right;">Page 352</p> <p>1 W. VIGILANTE</p> <p>2 Q. -- make sure my question --</p> <p>3 A. It's a -- I'm sorry. It's a quite</p> <p>4 common practice.</p> <p>5 (Reporter clarification -</p> <p>6 simultaneous speaking.)</p> <p>7 Q. Sorry. I'm sorry. What did you</p> <p>8 say?</p> <p>9 A. It was a common practice.</p> <p>10 Q. Okay. I just want to make sure my</p> <p>11 question specifically was clear, and I'm not</p> <p>12 asking about the Internet generally. I'm</p> <p>13 asking if you, yourself, in a litigation, say,</p> <p>14 have relied upon YouTube videos?</p> <p>15 A. I have relied upon YouTube videos</p> <p>16 as part of my investigation and evaluation of</p> <p>17 a --</p> <p>18 Q. Okay.</p> <p>19 A. -- litigation matter.</p> <p>20 Q. Are you aware of any publications,</p> <p>21 articles of any official human factors or</p> <p>22 ergonomics society that recognizes the use of</p> <p>23 YouTube videos in this fashion?</p> <p>24 A. I'm not aware of a specific</p> <p>25 reference to it, but, again, as a product</p>
<p style="text-align: right;">Page 353</p> <p>1 W. VIGILANTE</p> <p>2 developer with IBM, one of -- one -- there's</p> <p>3 an entire group dedicated to monitoring social</p> <p>4 media posts to determine and acquire</p> <p>5 product-related information with regards to</p> <p>6 how end users are actually using it in the</p> <p>7 field. So I used it as a product engineer.</p> <p>8 One of the development groups I was in</p> <p>9 spun-off a whole section of the team to do</p> <p>10 just that.</p> <p>11 Q. Would you agree with me that</p> <p>12 whether or not a user in the field as depicted</p> <p>13 in a YouTube video is or isn't using a product</p> <p>14 in the manner in which the manufacturer</p> <p>15 instructs, does that necessarily indicate that</p> <p>16 there is something inadequate or inappropriate</p> <p>17 about the instructions?</p> <p>18 MR. SKLARSKY: Let me just note an</p> <p>19 objection to the form, and maybe it's</p> <p>20 'cause I didn't hear the beginning, your</p> <p>21 voice may have trailed off, so...</p> <p>22 MR. SCHULTZ: Yeah, let -- I can</p> <p>23 rephrase it. It was not a particularly</p> <p>24 artful question.</p> <p>25 Q. In your experience, Mr. Vigilante,</p>	<p style="text-align: right;">Page 354</p> <p>1 W. VIGILANTE</p> <p>2 you've certainly encountered circumstances</p> <p>3 where a manufacturer provides complete, clear,</p> <p>4 adequate instructions and warnings and people</p> <p>5 still misuse the product; correct?</p> <p>6 A. It can happen, certainly.</p> <p>7 Q. And you -- by the way, have you</p> <p>8 done any research to determine whether people</p> <p>9 who post YouTube videos about connecting</p> <p>10 infusion sets to their bodies are</p> <p>11 representative of the patient population of</p> <p>12 Medtronic?</p> <p>13 A. And what kind of study would you</p> <p>14 be referring to?</p> <p>15 Q. Any kind of study.</p> <p>16 A. Well, from my review of the</p> <p>17 YouTube videos, they're the only ones I can</p> <p>18 find, and all of them were Medtronic Paradigm</p> <p>19 infusion set users. I know that there was</p> <p>20 a -- there was a couple more, but they were</p> <p>21 paid advertisements by Medtronic, so I didn't</p> <p>22 include them. So that's as much, you know,</p> <p>23 background research I went into choosing or</p> <p>24 using these YouTube videos or referencing</p> <p>25 these YouTube videos.</p>

<p style="text-align: right;">Page 355</p> <p>1 W. VIGILANTE</p> <p>2 Q. But so my question is: You have</p> <p>3 no information that the people who decided to</p> <p>4 go on YouTube and post these videos are in any</p> <p>5 way representative of the population of users</p> <p>6 of Medtronic insulin pumps and infusion sets;</p> <p>7 right?</p> <p>8 A. That's not true.</p> <p>9 Q. Well, how do you know they're</p> <p>10 representative?</p> <p>11 A. Well, the -- the user population</p> <p>12 is very large. If you're asking me whether or</p> <p>13 not they represent the mean or a standard</p> <p>14 deviation or two out from the mean, that's a</p> <p>15 different question, but they were all</p> <p>16 Medtronic users, they were all prescribed the</p> <p>17 infusion set, the Paradigm infusion set, so</p> <p>18 they were users. That's -- that's how I know</p> <p>19 they're representative of the population.</p> <p>20 Whether they -- I think your question is</p> <p>21 whether I know if they're the 95th percentile</p> <p>22 or the 5th percentile, and I don't, and I</p> <p>23 didn't need that information for the way I was</p> <p>24 referencing it.</p> <p>25 Q. The vast majority of these YouTube</p>	<p style="text-align: right;">Page 356</p> <p>1 W. VIGILANTE</p> <p>2 videos were posted after the June 2013 letter;</p> <p>3 is that correct?</p> <p>4 I guess it's not the vast</p> <p>5 majority, but several of them were; correct?</p> <p>6 A. Several of them were produced</p> <p>7 after.</p> <p>8 Q. And even with that information --</p> <p>9 first of all, do you know whether these people</p> <p>10 received that information?</p> <p>11 A. Yeah, I don't know if they were</p> <p>12 provided with the -- your patient letter or</p> <p>13 not.</p> <p>14 Q. Okay. And you don't know when</p> <p>15 they received IFUs and user guides and what</p> <p>16 the content of those might have been after</p> <p>17 June of 2013?</p> <p>18 A. I don't know.</p> <p>19 Q. So at least you'd concede it's</p> <p>20 possible that some of these people are</p> <p>21 removing the reservoir from the transfer guard</p> <p>22 in a manner contrary to what the instructions</p> <p>23 are possibly even after they've received the</p> <p>24 instructions in 2013 that you said were</p> <p>25 adequate?</p>
<p style="text-align: right;">Page 357</p> <p>1 W. VIGILANTE</p> <p>2 A. Yeah, I don't remember saying that</p> <p>3 they were adequate, so I think you're putting</p> <p>4 words into my mouth and -- but to answer your</p> <p>5 question, I don't know. I don't know if they</p> <p>6 received them or not.</p> <p>7 Q. Okay. You haven't issued an</p> <p>8 opinion one way or another as to the adequacy</p> <p>9 of the 2013 instructions and warnings;</p> <p>10 correct?</p> <p>11 A. I have not.</p> <p>12 Q. I'm sorry. Did you hear my</p> <p>13 question?</p> <p>14 A. I'm sorry. I answered. I said I</p> <p>15 have not.</p> <p>16 Q. Oh, I'm sorry. Okay.</p> <p>17 Did you review all of these videos</p> <p>18 yourself personally?</p> <p>19 A. Yes.</p> <p>20 Q. Did you see in any one of these</p> <p>21 videos any insulin spilling out on to the tops</p> <p>22 of any of the reservoirs?</p> <p>23 A. I don't recall.</p> <p>24 Q. Were you looking for it?</p> <p>25 A. I don't recall. I will say that I</p>	<p style="text-align: right;">Page 358</p> <p>1 W. VIGILANTE</p> <p>2 believe if I did see it, I would have noted</p> <p>3 it.</p> <p>4 MR. SCHULTZ: Okay. Thank you,</p> <p>5 Mr. Vigilante. I don't think I have</p> <p>6 anything further. I will pass the witness</p> <p>7 to Ms. Martinez, although I may have some</p> <p>8 follow up.</p> <p>9 EXAMINATION</p> <p>10 BY MS. MARTINEZ:</p> <p>11 Q. Hi, Mr. Vigilante, can you hear me</p> <p>12 okay?</p> <p>13 A. Yes, ma'am.</p> <p>14 Q. All right. Thank you.</p> <p>15 Mr. Vigilante, let me -- let me</p> <p>16 continue here with the videos. Let me refer</p> <p>17 your attention to the video that talks</p> <p>18 about -- in your report you say, "Another</p> <p>19 video depicts a child who fills his reservoir</p> <p>20 and then hands the unit to his mother to</p> <p>21 remove the air bubbles. After checking the</p> <p>22 reservoir for air bubbles, the mother hands</p> <p>23 the unit back to the child with the insulin</p> <p>24 vial on the bottom. The child takes the unit</p> <p>25 and pulls the reservoir off the transfer guard</p>

<p style="text-align: right;">Page 359</p> <p>1 W. VIGILANTE</p> <p>2 without seeming to ensure or care that the</p> <p>3 reservoir was held above the insulin vial."</p> <p>4 Let me -- since I've not seen that</p> <p>5 video, let me understand what you're saying</p> <p>6 that the video represents. The child -- when</p> <p>7 the mother handed the insulin -- or, I'm</p> <p>8 sorry, the reservoir and the insulin vial back</p> <p>9 to the child, the child kept the insulin vial</p> <p>10 on the bottom, is that correct, that is below</p> <p>11 the reservoir and the transfer guard?</p> <p>12 A. Yeah, he just -- if this is the</p> <p>13 unit with the insulin and reservoir, he just</p> <p>14 took it and grabbed it and popped it off</p> <p>15 (indicating). There was --</p> <p>16 Q. Okay.</p> <p>17 A. -- no thought. There was no</p> <p>18 decision made. There was no consideration.</p> <p>19 Q. All right. So let -- let me</p> <p>20 understand.</p> <p>21 So the answer to my question is,</p> <p>22 yes, the child kept the insulin vial below the</p> <p>23 transfer guard and the reservoir; correct?</p> <p>24 A. One more time.</p> <p>25 Q. Yes. So the answer to my original</p>	<p style="text-align: right;">Page 360</p> <p>1 W. VIGILANTE</p> <p>2 question is: The child kept the insulin vial</p> <p>3 below the reservoir and the transfer guard;</p> <p>4 correct --</p> <p>5 A. The child --</p> <p>6 Q. -- in that video?</p> <p>7 A. The child did keep the insulin</p> <p>8 vial below the reservoir.</p> <p>9 Q. Right, and -- and you've said in</p> <p>10 your report and you just repeated that there</p> <p>11 was no thought or care to do that. How is it</p> <p>12 that you determined that there was no thought</p> <p>13 or care on the part of the child to keep the</p> <p>14 insulin vial below the infusion -- I'm sorry,</p> <p>15 the reservoir and the transfer guard?</p> <p>16 A. Again, because he -- he -- he</p> <p>17 grabbed it off his mother and popped it off.</p> <p>18 He didn't take it from his mother and say,</p> <p>19 "Okay," and then pop off. There was no --</p> <p>20 there was no -- there's no pause. Again,</p> <p>21 there was no time for consideration, so just</p> <p>22 in the fact the way he took it from her and</p> <p>23 popped the top off is why I said --</p> <p>24 Q. Just --</p> <p>25 A. -- that there was -- it, you know,</p>
<p style="text-align: right;">Page 361</p> <p>1 W. VIGILANTE</p> <p>2 it appeared that way, it appeared that -- it</p> <p>3 appeared that he didn't -- you know, there was</p> <p>4 no action on his part to make sure it was the</p> <p>5 right way.</p> <p>6 Q. All right. So -- so to be fair,</p> <p>7 you're not inside this -- this child's mind;</p> <p>8 correct? You have no way of knowing what his</p> <p>9 thought process is, correct, or was?</p> <p>10 A. Yeah, I'm not in his mind. I can</p> <p>11 just tell you the way it appeared.</p> <p>12 Q. Right. So -- so basically your</p> <p>13 conclusion that there was no thought or care</p> <p>14 about keeping the vial of insulin below the</p> <p>15 transfer guard or -- and -- and the reservoir</p> <p>16 was based on the fact that the child did not</p> <p>17 pause and look at the insulin vial and the</p> <p>18 transfer guard and the reservoir before he</p> <p>19 disconnected, is that -- is that what you're</p> <p>20 saying?</p> <p>21 A. What I'm saying is based upon what</p> <p>22 I watched in the video, there didn't seem to</p> <p>23 be any consideration as to the orientation.</p> <p>24 He just took it and popped it off.</p> <p>25 Q. Yeah. And -- and --</p>	<p style="text-align: right;">Page 362</p> <p>1 W. VIGILANTE</p> <p>2 A. I can tell you from years of</p> <p>3 watching people use products if there's a</p> <p>4 deliber -- delibera -- deliberation or</p> <p>5 consideration, you expect a different -- to</p> <p>6 see a different result in the person's</p> <p>7 behavior. So based upon my training and</p> <p>8 experience and what I'm seeing, that's, you</p> <p>9 know, that's why I wrote it that way.</p> <p>10 Q. And -- and you don't know what</p> <p>11 information this child read or was given</p> <p>12 through training or through any other</p> <p>13 source --</p> <p>14 A. I think you --</p> <p>15 MR. SKLARSKY: We lost you. We --</p> <p>16 you're frozen.</p> <p>17 MR. SCHULTZ: We lost you.</p> <p>18 MR. SKLARSKY: Yeah.</p> <p>19 COURT REPORTER: She's frozen.</p> <p>20 MR. SKLARSKY: Frozen. What</p> <p>21 happened?</p> <p>22 THE WITNESS: It happened earlier.</p> <p>23 MR. SKLARSKY: We ought to go --</p> <p>24 THE VIDEOGRAPHER: Should we go off</p> <p>25 the video?</p>

<p style="text-align: right;">Page 363</p> <p>1 W. VIGILANTE</p> <p>2 MR. SKLARSKY: Yes.</p> <p>3 MR. SCHULTZ: Yeah.</p> <p>4 THE VIDEOGRAPHER: Off video, 12:37.</p> <p>5 (A recess is held from 12:36 p.m. to</p> <p>6 12:37 p.m.)</p> <p>7 THE VIDEOGRAPHER: Back on. 12:38.</p> <p>8 BY MS. MARTINEZ:</p> <p>9 Q. Okay. And, Mr. Vigilante, I</p> <p>10 think you told Mr. Schultz earlier that both</p> <p>11 as to this child and as to any of the</p> <p>12 participants in the other videos you mention</p> <p>13 in your report, that you are not aware of what</p> <p>14 information these users had on filling of the</p> <p>15 reservoir; correct?</p> <p>16 A. I don't know.</p> <p>17 Q. Right. And in -- in one of the</p> <p>18 videos you mention, you say that the -- the</p> <p>19 person in the video alerts the viewer of the</p> <p>20 need to flip the unit upside down before</p> <p>21 disconnecting the insulin vial from the</p> <p>22 transfer guard with the reservoir still</p> <p>23 attached.</p> <p>24 Am I understanding that this</p> <p>25 person in this particular video was</p>	<p style="text-align: right;">Page 364</p> <p>1 W. VIGILANTE</p> <p>2 instructing whoever was watching the video on</p> <p>3 the proper way, the proper orientation of the</p> <p>4 vial relative to the transfer guard and the</p> <p>5 reservoir during the disconnection process?</p> <p>6 A. I'm sorry. I couldn't figure out</p> <p>7 where you were referring to in my report.</p> <p>8 Q. Sure. Let me -- let me -- let me</p> <p>9 tell you. It's Page 2 of 5 of your</p> <p>10 supplemental report --</p> <p>11 A. Okay.</p> <p>12 Q. -- in the second full paragraph,</p> <p>13 second sentence.</p> <p>14 You see that?</p> <p>15 A. Yes, ma'am.</p> <p>16 Q. Okay. And so am I understanding</p> <p>17 properly what you're trying to convey in this</p> <p>18 paragraph, which is your impression that the</p> <p>19 person in that video was instructing the users</p> <p>20 or the viewers of the video the proper way to</p> <p>21 orient the insulin vial with respect to the</p> <p>22 transfer guard and the reservoir during the</p> <p>23 disconnection process? In other words, the</p> <p>24 vial was -- was below the reservoir and the</p> <p>25 transfer guard?</p>
<p style="text-align: right;">Page 365</p> <p>1 W. VIGILANTE</p> <p>2 MR. SKLARSKY: I'm sorry. What --</p> <p>3 what's the question though? What -- what</p> <p>4 is --</p> <p>5 MS. MARTINEZ: The -- the question</p> <p>6 is: Am I interpreting correctly what</p> <p>7 Mr. Vigilante is trying to say that the</p> <p>8 video depicted. I just want to make sure I</p> <p>9 understand what his report says.</p> <p>10 Q. Does -- are -- are you conveying</p> <p>11 here that this video showed that the insulin</p> <p>12 vial was below the reservoir and the -- and</p> <p>13 the transfer guard?</p> <p>14 A. No. The -- the first sentence of</p> <p>15 the paragraph, if we're talking about the same</p> <p>16 paragraph, says, "In two of the videos the</p> <p>17 user held the insulin vial, transfer guard,</p> <p>18 and reservoir sideways."</p> <p>19 So, again, if this is our unit,</p> <p>20 they're holding it like this (indicating) as</p> <p>21 opposed to like this (indicating).</p> <p>22 In one of the videos, the user</p> <p>23 removes the insulin vial from the transfer</p> <p>24 guard first, which is not the correct way to</p> <p>25 do it according to the IFU.</p>	<p style="text-align: right;">Page 366</p> <p>1 W. VIGILANTE</p> <p>2 Q. Right. That -- that --</p> <p>3 A. Now, I'm not -- hold on. Hold on.</p> <p>4 The view -- in that -- in that</p> <p>5 video, the user alerts the viewer, so he</p> <p>6 tells -- tells -- tells the video -- tells the</p> <p>7 camera that you need to flip the unit upside</p> <p>8 down before disconnecting the insulin vial</p> <p>9 from the transfer guard, but then he</p> <p>10 subsequently turned it sideways before he took</p> <p>11 the insulin vial from the transfer guard so --</p> <p>12 Q. Okay.</p> <p>13 A. -- he -- he --</p> <p>14 Q. So --</p> <p>15 A. -- he -- he told us the insulin</p> <p>16 vial had to be flipped, but then he didn't</p> <p>17 flip it upside down or what have you. He did</p> <p>18 it sideways and he believed that you're</p> <p>19 supposed to take the insulin vial off the</p> <p>20 transfer guard before the reservoir, according</p> <p>21 to what he said and what he did. That's all</p> <p>22 I'm trying to say.</p> <p>23 Q. All right. So you keep talking</p> <p>24 about flipping without orientation, so in</p> <p>25 this -- in this video the viewer tells -- or</p>

<p style="text-align: right;">Page 367</p> <p>1 W. VIGILANTE</p> <p>2 I'm sorry. The -- the person in the video</p> <p>3 tells the viewer that the insulin vial is</p> <p>4 supposed to be on the bottom of the reservoir</p> <p>5 and the -- and the transfer guard; correct?</p> <p>6 A. I'm going to have to say that I</p> <p>7 don't specifically say it in the paragraph, so</p> <p>8 I don't know for sure, but I would think that</p> <p>9 my intention was is that he did -- he did mean</p> <p>10 to tell the viewer that the insulin should</p> <p>11 be -- vial should be on the bottom. I can't</p> <p>12 guarantee 100 percent, but I think that's --</p> <p>13 Q. Okay.</p> <p>14 A. -- that would be correct.</p> <p>15 Q. All right. And so let's assume</p> <p>16 that that -- that that's what you intended to</p> <p>17 convey here. So even though this particular</p> <p>18 person in the video knew the proper way to</p> <p>19 orient the vial, he still disregarded those</p> <p>20 instructions and when disconnecting the</p> <p>21 transfer guard from the vial turned it</p> <p>22 sideways. Is that the message you're trying</p> <p>23 to convey?</p> <p>24 A. No. I'm not. I'm -- I'm trying</p> <p>25 to convey, again, that YouTube videos are</p>	<p style="text-align: right;">Page 368</p> <p>1 W. VIGILANTE</p> <p>2 showing that the more natural way of taking</p> <p>3 these things off is -- is with the reservoir</p> <p>4 on the bottom or in some cases sideways as</p> <p>5 opposed to being on top which we talked about</p> <p>6 last deposition.</p> <p>7 So the YouTube videos were -- you</p> <p>8 know, I -- I did a -- did a search to find all</p> <p>9 them that I could find that were not done by</p> <p>10 Medtronic professionally paid people, and I</p> <p>11 documented what I saw in those videos; and the</p> <p>12 majority of the videos I saw them doing it the</p> <p>13 wrong way, and I saw them doing it the way you</p> <p>14 would expect based upon natural tendencies,</p> <p>15 trying to be as efficient and as comfortable</p> <p>16 as possible, everything I talked about in the</p> <p>17 report and in my task analysis.</p> <p>18 Q. Sir, just to be clear, in some of</p> <p>19 these videos, the people in the videos were</p> <p>20 doing it exactly correctly as the -- in</p> <p>21 accordance with the IFUs; correct?</p> <p>22 A. I will state it this way: In four</p> <p>23 of the videos the user held the reservoir</p> <p>24 above the insulin vial before removing it from</p> <p>25 the transfer guard. I didn't see and watch to</p>
<p style="text-align: right;">Page 369</p> <p>1 W. VIGILANTE</p> <p>2 determine if they followed the IFU completely</p> <p>3 for the whole process, but with regard to</p> <p>4 Step 6 as it relates to our case, they did</p> <p>5 hold the reservoir above the insulin vial</p> <p>6 before removing it from the transfer guard.</p> <p>7 Q. Okay. Mr. Vigilante, are you</p> <p>8 aware that Unomedical had nothing to do with</p> <p>9 the design of the P-cap?</p> <p>10 A. It's my understanding that's</p> <p>11 correct.</p> <p>12 Q. Okay. And do you understand that</p> <p>13 Unomedical had nothing to do with the</p> <p>14 manufacturing of the P-cap when the -- when</p> <p>15 the 510(k) for the Silhouette infusion set was</p> <p>16 submitted to the FDA?</p> <p>17 A. I'm aware that at one point</p> <p>18 Unomedical was not manufacturing the P-cap,</p> <p>19 but I can't give you a reference with respect</p> <p>20 to the 501(k).</p> <p>21 Q. Are you aware that until</p> <p>22 approximately 2006 Medtronic was manufacturing</p> <p>23 the P-cap and providing it to Unomedical for</p> <p>24 assembly into the finished infusion set?</p> <p>25 A. Yeah, again, I -- I know that at</p>	<p style="text-align: right;">Page 370</p> <p>1 W. VIGILANTE</p> <p>2 one point Medtronic was manufacturing the</p> <p>3 P-cap, and then eventually that shifted to</p> <p>4 Unomedical manufacturing it, and I don't know</p> <p>5 offhand what that time frame is.</p> <p>6 Q. All right. Have you reviewed the</p> <p>7 IFU for the infusion set that was shipped by</p> <p>8 Medtronic with Ms. Dennert's Silhouette</p> <p>9 infusion set?</p> <p>10 A. Yes.</p> <p>11 Q. Is that noted in your report?</p> <p>12 A. I don't know if it is or is not,</p> <p>13 but if you give me a moment, I'll be happy to</p> <p>14 look.</p> <p>15 (Reviewing document.)</p> <p>16 I have -- under Page 3 I have IFUs</p> <p>17 for Paradigm reservoir and infusion set.</p> <p>18 Q. Okay. And I would like for you</p> <p>19 to tell me what, if any, criticisms you have</p> <p>20 of the infusion set IFU. I understand that</p> <p>21 you've gone over criticisms you have about the</p> <p>22 IFU for the reservoir, but I want to know</p> <p>23 specifically as to the infusion set IFU what</p> <p>24 criticisms, if any, you have.</p> <p>25 A. I just want to append my last</p>

<p style="text-align: right;">Page 371</p> <p>1 W. VIGILANTE</p> <p>2 answer that I also note in my material</p> <p>3 reviewed that I had exemplar Paradigm</p> <p>4 reservoir and infusion set. So those are the</p> <p>5 ones, my understanding is, were -- were the --</p> <p>6 were the sets that Mrs. Dennert had at the</p> <p>7 time of the incident.</p> <p>8 Q. Okay. Did you hear my last</p> <p>9 question?</p> <p>10 A. I'm sorry. You're going to have</p> <p>11 to do that one more time.</p> <p>12 Q. Sure. No worries.</p> <p>13 I would like to know each and</p> <p>14 every criticism, if any, that you have of the</p> <p>15 IFU for the Silhouette infusion set.</p> <p>16 A. Oh, yeah, I don't have -- as</p> <p>17 opposed to the Paradigm IFU, the IFU for the</p> <p>18 infusion set itself, at least the instructions</p> <p>19 it's providing are related to attaching it to</p> <p>20 the cannula and putting it in your skin, so</p> <p>21 it's not really related to the prime fill</p> <p>22 anomaly, so I didn't get into whether or not</p> <p>23 the IFU for the infusion set, the instructions</p> <p>24 it provides with respect to connecting it to</p> <p>25 the -- to the body were adequate or not.</p>	<p style="text-align: right;">Page 372</p> <p>1 W. VIGILANTE</p> <p>2 Q. Okay.</p> <p>3 A. The issue I was looking at was</p> <p>4 the -- related to the prime fill anomaly.</p> <p>5 Q. Right. And so -- so as -- as I</p> <p>6 understand it, your criticisms that you've</p> <p>7 expressed both in your report and in your</p> <p>8 deposition have been directed at the IFU for</p> <p>9 the reservoir, correct, the Paradigm</p> <p>10 reservoir?</p> <p>11 A. Well, yes and no.</p> <p>12 Q. Well, if you have any criticism</p> <p>13 specifically as to the infusion set IFU, I</p> <p>14 would like to hear those, please.</p> <p>15 A. Well -- well, I think you're</p> <p>16 missing the point. The point is, is that it's</p> <p>17 a system developed and sold by and introduced</p> <p>18 to the stream of commerce by Unomedical and</p> <p>19 Medtronic. So the Paradigm isn't used in a</p> <p>20 vacuum. The Paradigm reservoir isn't used in</p> <p>21 a vacuum. The infusion set isn't used in a</p> <p>22 vacuum. It's a system. And it -- to me it</p> <p>23 looked like, you know, however you guys</p> <p>24 decided between you guys, you were going to</p> <p>25 provide the information related to connecting</p>
<p style="text-align: right;">Page 373</p> <p>1 W. VIGILANTE</p> <p>2 the P-cap to the reservoir in the IFU for the</p> <p>3 Paradigm, but you sure as -- could have done</p> <p>4 both, and I don't have an opinion regarding</p> <p>5 that. But it's -- you know, it's the entire</p> <p>6 connection system that's the -- that's at</p> <p>7 issue, and that's where my opinions are</p> <p>8 with -- with regard to the -- filling the</p> <p>9 reservoir and connecting it to the P-cap which</p> <p>10 is a integrated part of the infusion set.</p> <p>11 Q. All right. So let -- let -- let</p> <p>12 me then start with you understand that</p> <p>13 Unomedical had nothing to do with the design</p> <p>14 of the reservoir?</p> <p>15 THE WITNESS: Did you have a</p> <p>16 question? I'm sorry?</p> <p>17 COURT REPORTER: I think we lost the</p> <p>18 sound again.</p> <p>19 THE WITNESS: Okay.</p> <p>20 MR. SCHULTZ: Ileana, can you hear</p> <p>21 us? Yep, she's gone.</p> <p>22 THE VIDEOGRAPHER: Should we go off</p> <p>23 the record?</p> <p>24 MR. SCHULTZ: Give her two seconds.</p> <p>25 MS. MARTINEZ: I lost you again.</p>	<p style="text-align: right;">Page 374</p> <p>1 W. VIGILANTE</p> <p>2 I'm --</p> <p>3 THE WITNESS: Can you see us.</p> <p>4 MS. MARTINEZ: Okay. I'm sorry.</p> <p>5 It just -- it just cuts out and I have no</p> <p>6 control over it. I apologize.</p> <p>7 BY MS. MARTINEZ:</p> <p>8 Q. I think my question was: Do you</p> <p>9 understand that Unomedical had nothing to do</p> <p>10 with the design of the reservoir?</p> <p>11 A. Yes, it's -- that's correct.</p> <p>12 Q. Okay. And you understand that</p> <p>13 Unomedical had nothing to do with the</p> <p>14 manufacture of the reservoir?</p> <p>15 A. I believe that's correct, too.</p> <p>16 Q. Okay. And do you understand that</p> <p>17 Unomedical had nothing to do with the design</p> <p>18 of the insulin pump?</p> <p>19 A. I do know that.</p> <p>20 Q. And -- and by the insulin pump and</p> <p>21 the reservoir, I'm not only talking about the</p> <p>22 one that Ms. Dennert was using, but any</p> <p>23 insulin pump and any reservoir of the Paradigm</p> <p>24 family.</p> <p>25 A. Yeah, I haven't seen anything to</p>

<p style="text-align: right;">Page 375</p> <p>1 W. VIGILANTE</p> <p>2 suggest that Unomedical designed the pump or</p> <p>3 the reservoir.</p> <p>4 Q. Okay. And you also -- and you</p> <p>5 also understand that Unomedical neither</p> <p>6 manufactured the pump, and you've already</p> <p>7 acknowledged that you have no information that</p> <p>8 it manufactured the reservoir; correct?</p> <p>9 A. I believe that's correct.</p> <p>10 Q. Okay. Do you understand that</p> <p>11 Unomedical manufactured the infusion set, the</p> <p>12 tubing part until 2006 and obtained the P-cap</p> <p>13 connector from Medtronic to assemble it into</p> <p>14 its infusion set?</p> <p>15 A. I knew that was correct, but I</p> <p>16 don't know what the time frame was.</p> <p>17 Q. Understood. So I would like for</p> <p>18 you to tell me, again, my original -- with --</p> <p>19 with -- with the understanding that I now know</p> <p>20 that you've got about Unomedical's role or --</p> <p>21 or lack thereof in the insulin pump and the</p> <p>22 reservoir and in the design of the P-cap, I</p> <p>23 would like for you to tell me what, if any,</p> <p>24 criticisms you have specifically of the</p> <p>25 infusion set IFU.</p>	<p style="text-align: right;">Page 376</p> <p>1 W. VIGILANTE</p> <p>2 And I'm not making you try to have</p> <p>3 any criticisms. You may not have any</p> <p>4 criticisms specifically about the IFU for the</p> <p>5 infusion set.</p> <p>6 MR. SKLARSKY: Well, let me just put</p> <p>7 an objection on the record. The other</p> <p>8 aspect is or whether or not he evaluated it</p> <p>9 for this case.</p> <p>10 Q. Okay. Go ahead, sir.</p> <p>11 A. Yeah. So as I tried explaining</p> <p>12 earlier, the -- the specific IFU that came</p> <p>13 with the infusion set as opposed to the IFU</p> <p>14 for the Paradigm reservoir didn't address the</p> <p>15 issue related to the prime fill anomaly. The</p> <p>16 IFU for the Paradigm reservoir did. So that's</p> <p>17 where the focus of my attention was.</p> <p>18 My criticism of Unomedical is that</p> <p>19 the infusion set and reservoir are a system,</p> <p>20 and adequate warning and instruction needed to</p> <p>21 be provided for that system, and because the</p> <p>22 IFU for the Paradigm pump that -- that was</p> <p>23 shipped with the Paradigm pump wasn't</p> <p>24 adequate, that is my opinion, that Unomedical</p> <p>25 failed to provide adequate instruction and</p>
<p style="text-align: right;">Page 377</p> <p>1 W. VIGILANTE</p> <p>2 warning. It has --</p> <p>3 Q. Okay.</p> <p>4 A. -- it has -- you know, it --</p> <p>5 that's -- that's what I was trying to explain.</p> <p>6 Q. Okay. So -- so you don't have --</p> <p>7 again, as to my question, the IFU, the paper,</p> <p>8 the written IFU, what I understand is that you</p> <p>9 don't have any criticisms of the IFU itself.</p> <p>10 What you're criticizing is Medtronic's IFU for</p> <p>11 the reservoir.</p> <p>12 A. I think the best way to express it</p> <p>13 is that my criticisms are with respect to the</p> <p>14 instructions and warnings that Unomedical and</p> <p>15 Medtronic provided with respect to the prime</p> <p>16 fill anomaly hazard.</p> <p>17 Q. All right. I want to -- I want</p> <p>18 to -- you understand that, that Medtronic and</p> <p>19 Unomedical are separate and independent</p> <p>20 companies? Do you understand that?</p> <p>21 A. I understand they're two different</p> <p>22 companies.</p> <p>23 Q. Okay. And we've already gone</p> <p>24 through the products that Unomedical makes and</p> <p>25 provides to Medtronic and ones that Medtronic</p>	<p style="text-align: right;">Page 378</p> <p>1 W. VIGILANTE</p> <p>2 designs and manufactures entirely on its own;</p> <p>3 correct? And so what I want to know is,</p> <p>4 again, just my question is focussing on the</p> <p>5 infusion set IFU, do you have any criticisms?</p> <p>6 Are you going to offer any opinions about the</p> <p>7 paper, about the IFU for the infusion set?</p> <p>8 A. Yes. So, again, I didn't evaluate</p> <p>9 the IFU specifically that accompanied the</p> <p>10 infusion set. I evaluated the warnings and</p> <p>11 instructions that Unomedical and Medtronic</p> <p>12 provided with respect to the prime fill</p> <p>13 anomaly hazard.</p> <p>14 Q. All right. So specifically as to</p> <p>15 the IFU, what information do you believe that</p> <p>16 the IFU for the infusion set should have</p> <p>17 contained that it does not?</p> <p>18 A. Yeah, if the intent of Unomedical</p> <p>19 and Medtronic was to cover the warnings and</p> <p>20 instructions related to the connection of the</p> <p>21 reservoir to the P-cap and infusion set was</p> <p>22 going to be done in the Paradigm reservoir,</p> <p>23 then that's my understanding. That's the way</p> <p>24 I looked at it. That's the way I understood</p> <p>25 it. I didn't evaluate the IFU for the</p>

<p style="text-align: right;">Page 379</p> <p>1 W. VIGILANTE</p> <p>2 infusion set because it had nothing to do with</p> <p>3 the connection of the reservoir to the P-cap</p> <p>4 connector. It had to do with the insertion of</p> <p>5 the infusion set to the skin, and that wasn't</p> <p>6 related to the hazard.</p> <p>7 Q. Okay. So then you -- you</p> <p>8 understand that in Unomedical's infusion set</p> <p>9 IFU, it directs the user to the pump user</p> <p>10 guide to install the infusion set and the</p> <p>11 reservoir system into the pump? Did you see</p> <p>12 that there?</p> <p>13 A. You're going to have to let me</p> <p>14 know where that's at. I've got it pulled up</p> <p>15 on my screen, if you can let me know where</p> <p>16 it's at.</p> <p>17 Q. It should be -- and, again, I</p> <p>18 don't know what document you've got in front</p> <p>19 of you, can you --</p> <p>20 MR. SKLARSKY: Is there an exhibit</p> <p>21 that -- that --</p> <p>22 Q. It -- it should be at the very</p> <p>23 beginning somewhere.</p> <p>24 MR. SKLARSKY: I'm sorry. Is -- was</p> <p>25 it marked at -- at the prior deposition as</p>	<p style="text-align: right;">Page 380</p> <p>1 W. VIGILANTE</p> <p>2 an exhibit?</p> <p>3 MS. MARTINEZ: You know, I -- I</p> <p>4 don't know if it was. I don't think so.</p> <p>5 MR. SKLARSKY: Was it sent --</p> <p>6 Q. Can you take --</p> <p>7 MR. SKLARSKY: Was it --</p> <p>8 Q. -- can you take a look at the</p> <p>9 infusion set IFU that you have listed in your</p> <p>10 report as having reviewed?</p> <p>11 A. I'm not sure what you're asking.</p> <p>12 I'm -- I'm -- I have a copy of the infusion</p> <p>13 set IFU.</p> <p>14 Q. Right.</p> <p>15 A. It's my understanding it's a --</p> <p>16 it's a picture of the IFU that was in the</p> <p>17 exemplar I -- infusion set that Mrs. Dennert</p> <p>18 had at the time of the incident --</p> <p>19 Q. Right.</p> <p>20 A. -- and I believe --</p> <p>21 Q. And you --</p> <p>22 A. -- I have another copy of that IFU</p> <p>23 that was produced by Medtronic and/or</p> <p>24 Unomedical. I'm going to say Medtronic 'cause</p> <p>25 it's listed as -- under my Medtronic heading</p>
<p style="text-align: right;">Page 381</p> <p>1 W. VIGILANTE</p> <p>2 in the -- in discovery. So that --</p> <p>3 Q. All right.</p> <p>4 A. -- that's how I would identify</p> <p>5 them.</p> <p>6 Q. Sure. And do you see language</p> <p>7 there to the effect that the IFU for the</p> <p>8 infusion set refers the user to the pump user</p> <p>9 guide to install the infusion set and</p> <p>10 reservoir system into the pump? Do you see</p> <p>11 that?</p> <p>12 A. I don't. That's why I asked you</p> <p>13 where it was.</p> <p>14 Q. Okay. But you don't -- you don't</p> <p>15 see that at all, anywhere there?</p> <p>16 A. I don't see it. I don't -- I'm --</p> <p>17 I'm -- you know, I don't want to mislead you,</p> <p>18 but I don't see it.</p> <p>19 Q. Okay. Well, let me ask you this:</p> <p>20 Assume for me, please, that the infusion set</p> <p>21 IFU that Ms. Dennert received with her</p> <p>22 Silhouette infusion set referred her to the</p> <p>23 Medtronic pump user guide in order to set up</p> <p>24 the infusion set and the reservoir system with</p> <p>25 the pump.</p>	<p style="text-align: right;">Page 382</p> <p>1 W. VIGILANTE</p> <p>2 Okay?</p> <p>3 A. Okay.</p> <p>4 Q. Is -- do you have any criticisms</p> <p>5 about Unomedical referring the user to the</p> <p>6 reservoir IFU for purposes of filling the</p> <p>7 reservoir with insulin from the insulin vial</p> <p>8 and connecting that reservoir to the infusion</p> <p>9 set?</p> <p>10 A. I'm sorry. You lost me.</p> <p>11 Q. Sure. Assume for me that the</p> <p>12 infusion set IFU that Ms. Dennert had</p> <p>13 available to her with the Silhouette infusion</p> <p>14 set referred her to the Medtronic reservoir</p> <p>15 IFU for purposes of instructing her how to</p> <p>16 connect the infusion set to the reservoir.</p> <p>17 A. Okay.</p> <p>18 Q. Okay. Do you have any criticisms</p> <p>19 of Unomedical doing that?</p> <p>20 A. I don't think so.</p> <p>21 Q. Okay. And I understand that --</p> <p>22 that you do criticize the -- the reservoir</p> <p>23 IFU, but in terms of just Unomedical referring</p> <p>24 the user to the reservoir IFU, you don't have</p> <p>25 any criticisms of that?</p>

<p style="text-align: right;">Page 383</p> <p>1 W. VIGILANTE</p> <p>2 A. As I just said, I don't think so.</p> <p>3 If that's what the IFU for the infusion set</p> <p>4 said refer to the IFU for the reservoir, for</p> <p>5 connection of the P-cap to the reservoir,</p> <p>6 that's fine.</p> <p>7 Q. Okay. So then, again, my original</p> <p>8 question was: As -- you know, when you get to</p> <p>9 trial, are you going to say to the jury that</p> <p>10 Unomedical should have had certain pictures or</p> <p>11 language or infusion set -- I'm sorry, or --</p> <p>12 or pictures or language or warnings in its IFU</p> <p>13 for the infusion set? And if so, I would like</p> <p>14 to know what those are. And if not, just let</p> <p>15 me know.</p> <p>16 A. Yeah, I wasn't planning on</p> <p>17 bringing up the IFU for the infusion set to</p> <p>18 say that it needed X, Y, or Z.</p> <p>19 Q. Okay. And so, again, throughout</p> <p>20 your report you say Medtronic and Unomedical</p> <p>21 should have done this and should have done</p> <p>22 that. What exactly then -- now putting the</p> <p>23 IFU, right, the written IFU apart because</p> <p>24 we've already covered that and I understand</p> <p>25 your position, I would like to understand</p>	<p style="text-align: right;">Page 384</p> <p>1 W. VIGILANTE</p> <p>2 exactly what Unomedical should have done in</p> <p>3 terms of warnings or instructions.</p> <p>4 A. Yeah, again, they should have made</p> <p>5 sure that adequate instructions were provided</p> <p>6 if they were going to rely upon the IFU for</p> <p>7 the reservoir, that they were provided in that</p> <p>8 IFU to alert people to the hazard and how to</p> <p>9 avoid it. That's the simplest --</p> <p>10 Q. And --</p> <p>11 A. -- way I can put it.</p> <p>12 Q. All right. And -- and how in your</p> <p>13 opinion should Unomedical have --</p> <p>14 (Technical difficulties.)</p> <p>15 MR. SKLARSKY: Can you -- you</p> <p>16 trailed off. We lost you again I think.</p> <p>17 That is the problem with these deps.</p> <p>18 THE WITNESS: It's apparently</p> <p>19 whenever she's talking.</p> <p>20 MR. SKLARSKY: Okay. We're off --</p> <p>21 MS. MARTINEZ: I am --</p> <p>22 MR. SKLARSKY: Yeah.</p> <p>23 MS. MARTINEZ: I am so sorry. Let</p> <p>24 me -- let me contact my IT person. This is</p> <p>25 ridiculous.</p>
<p style="text-align: right;">Page 385</p> <p>1 W. VIGILANTE</p> <p>2 THE WITNESS: You guys want to take</p> <p>3 a little break here?</p> <p>4 MS. MARTINEZ: Yes, let's -- let's</p> <p>5 do that. Let's just take five. Thank you.</p> <p>6 THE VIDEOGRAPHER: Off video. The</p> <p>7 time, 13:05.</p> <p>8 (A recess is held from 1:04 p.m. to</p> <p>9 1:15 p.m.)</p> <p>10 THE VIDEOGRAPHER: We are back on</p> <p>11 the record. The date September 23rd, 2016.</p> <p>12 The time 13:15.</p> <p>13 MS. MARTINEZ: Ms. Court Reporter,</p> <p>14 can you read the last question that was</p> <p>15 pending?</p> <p>16 (The following portion of the record</p> <p>17 is read by the Court Reporter:</p> <p>18 "QUESTION: All right. And how in</p> <p>19 your opinion should Unomedical have --")</p> <p>20 MS. MARTINEZ: Okay.</p> <p>21 MR. SKLARSKY: That gets us really</p> <p>22 far.</p> <p>23 MS. MARTINEZ: So why don't you read</p> <p>24 his answer.</p> <p>25 THE WITNESS: Didn't have an answer.</p>	<p style="text-align: right;">Page 386</p> <p>1 W. VIGILANTE</p> <p>2 Your question was never finished.</p> <p>3 MS. MARTINEZ: No, no. I'm sorry.</p> <p>4 The answer to the question before that.</p> <p>5 (The following portion of the record</p> <p>6 is read by the Court Reporter:</p> <p>7 "ANSWER: Yeah, again, they should</p> <p>8 have made sure that adequate instructions</p> <p>9 were provided if they were going to rely</p> <p>10 upon the IFU for the reservoir, that they</p> <p>11 were provided in that IFU to alert people</p> <p>12 to the hazard and how to avoid it. That's</p> <p>13 the simplest way I can put it.")</p> <p>14 BY MS. MARTINEZ:</p> <p>15 Q. Okay. And the question -- and my</p> <p>16 follow-up question was: Please explain to me</p> <p>17 how it is that Unomedical should have done</p> <p>18 that.</p> <p>19 A. In conjunction with Medtronic.</p> <p>20 Q. What do you mean by that?</p> <p>21 A. It's a system comprised of parts</p> <p>22 from Unomedical and Medtronic that Unomedical</p> <p>23 is manufacturing and shipping for Medtronic.</p> <p>24 You should have ensured that the warnings and</p> <p>25 instructions that were necessary were</p>

W. VIGILANTE

provided; and if you were going to rely upon the IFU for the Paradigm pump, then you should have made sure it was in there. If you're going to use it another way, then you should have made sure it was done through the other way, but you had a responsibility to provide, excuse me, to provide adequate instructions and warnings and you should have made sure it was done.

Q. Okay. So your testimony is that Unomedical had a duty to provide instructions regarding a product that is the reservoir that was not Unomedical's product?

A. No. I said they had a responsibility to ensure that adequate instructions and warnings were provided. If they relied upon Medtronic to do so, that's fine, but they needed to ensure that adequate instructions and warnings were provided.

Q. Okay. And when you say "adequate instructions and warnings," I'm assuming you are talking about what is at issue, according to you, in this case which is the -- the reservoir and the vial, the insulin vial

W. VIGILANTE

orientation; correct?

A. The prime fill anomaly.

Q. All right. And so tell me exactly how Unomedical should have ensured that, according to you, there were proper instructions and warnings about a reservoir that is not Unomedical's product, it does not design it, and it does not manufacture it.

A. I understand that Unomedical doesn't manufacture the reservoir. However, the reservoir connects to the infusion set that is a system. Therefore, it's your system, your half of the system that the hazard's associated with. Because there was a hazard associated with your system or the -- your product that was part of a system, you had a responsibility to ensure adequate instructions and warnings were provided. Whether you did that by relying upon the Paradigm IF -- Paradigm reservoir IFU or if you did that independent of Medtronic, it was your responsibility to ensure people were warned and adequately instructed.

Q. All right. And -- and when you

W. VIGILANTE

say "were warned," you are talking about the prime fill anomaly issue; correct?

A. Yes.

Q. All right. And when is it your understanding that Unomedical first learned about the prime fill anomaly?

A. I have testimony from your corporate designee. Let me see if I can grab that real quick.

According to Rabi Gharabli -- and I apologize for not pronouncing his name correctly.

Q. You did fine.

A. I'm sorry?

Q. You did fine.

A. -- Unomedical learned about the issue related to the membrane getting wet affecting dosage after it became public.

Q. And -- and did you understand that after it became public, it means after the June 2013 warning letters and ultimate recall; correct?

A. After it became public. I don't think he defined what "public" means, but

W. VIGILANTE

I'm -- I'll agree with you it was sometime in 2012, 2013 time frame.

Q. Okay. So -- and -- and 2013 was certainly after Ms. Dennert's incident; correct?

A. Sure.

Q. Right. And so is it your testimony that Unomedical should have warned about the prime fill anomaly before they even knew about it?

A. No.

Q. Okay. So -- so you're saying that Unomedical should have ensured that Medtronic issued proper warnings and instructions related to the prime fill anomaly at what point in time?

A. When they developed the system which was back in 2001 time frame, 2000, 2001.

Q. Okay. What do you mean "when they developed the system"?

A. When you guys developed the system between Medtronic coming up with the P-cap and sending it to Unomedical to attach to an infusion set that was going to be used with a

<p style="text-align: right;">Page 391</p> <p>1 W. VIGILANTE</p> <p>2 reservoir, that's when you guys should have</p> <p>3 been doing your risk analysis and human</p> <p>4 factors analysis as noted in my report and</p> <p>5 you --</p> <p>6 Q. Okay.</p> <p>7 A. -- should have identified the</p> <p>8 hazard then and you should have provided or</p> <p>9 ensured warnings, adequate warnings and</p> <p>10 instructions were provided at that point.</p> <p>11 Q. All right. So do you know what</p> <p>12 risk analysis was reviewed by Unomedical</p> <p>13 before the 510(k) was submitted to the FDA or</p> <p>14 at the time?</p> <p>15 A. Give me a moment.</p> <p>16 (Reviewing document.)</p> <p>17 The only thing I know is that</p> <p>18 Mr. Rabi Gharabli testified that he's not</p> <p>19 aware of any human factors testing to</p> <p>20 determine proper use of the infusion set and</p> <p>21 does not remember any human factors studies or</p> <p>22 analysis involving the Paradigm Quick-set</p> <p>23 infusion set; and that -- that's his testimony</p> <p>24 on Page 67.</p> <p>25 Q. All right. My question was: Are</p>	<p style="text-align: right;">Page 392</p> <p>1 W. VIGILANTE</p> <p>2 you aware of any risk analysis that Unomedical</p> <p>3 had in its possession or reviewed prior to or</p> <p>4 at the time that it submitted its 510(k)</p> <p>5 from -- to the FDA for the infusion set?</p> <p>6 A. Yeah, based upon my reading of</p> <p>7 Mr. Gharabli, I don't think they did any or</p> <p>8 had any.</p> <p>9 Q. Okay. So -- okay. So that's the</p> <p>10 basis, you're saying that Mr. Gharabli said</p> <p>11 that?</p> <p>12 A. I'm saying that he didn't testify</p> <p>13 to that they had any or that they did any.</p> <p>14 Q. Do you know what page of his</p> <p>15 deposition that testimony's at?</p> <p>16 A. That's what I'm saying. There's</p> <p>17 no testimony about it. There -- there's no</p> <p>18 testimony that they did a risk analysis.</p> <p>19 There's no testimony that he reviewed any risk</p> <p>20 analysis.</p> <p>21 I just noted that he didn't any --</p> <p>22 he wasn't aware of any human factors testing</p> <p>23 done.</p> <p>24 Q. Now, is it your understanding --</p> <p>25 tell -- are you aware of any FDA or other</p>
<p style="text-align: right;">Page 393</p> <p>1 W. VIGILANTE</p> <p>2 regulations or industry cut -- oh, God.</p> <p>3 A. Oops.</p> <p>4 (Technical difficulties.)</p> <p>5 A. Seems we --</p> <p>6 Q. Apologies again.</p> <p>7 A. It's okay.</p> <p>8 Q. Sorry. We got disconnected again.</p> <p>9 Are you aware of any FDA</p> <p>10 regulations or industry standards and customs</p> <p>11 that required Unomedical to conduct a human</p> <p>12 factors analysis at the time that the -- that</p> <p>13 it submitted the infusion 510(k) to the FDA?</p> <p>14 A. Yeah, I'm not aware of the FDA</p> <p>15 requiring it. I remem -- I -- I'm aware that</p> <p>16 they recommended it and it was a guideline</p> <p>17 provided by the FDA that it does.</p> <p>18 Q. Okay. What guideline is that?</p> <p>19 A. Well, hold on a minute.</p> <p>20 (Reviewing document.)</p> <p>21 In 2000 the FDA published their</p> <p>22 guidance for industry and FDA reviewers on</p> <p>23 medical device use, safety, incorporating</p> <p>24 human factors, engineering, and to risk</p> <p>25 management avail -- risk management</p>	<p style="text-align: right;">Page 394</p> <p>1 W. VIGILANTE</p> <p>2 availability within the Federal Register.</p> <p>3 Q. And certainly you know that FDA</p> <p>4 guidance is not an FDA regulation; correct?</p> <p>5 A. I'm sorry. Yes, it was a</p> <p>6 guidance, not a regulation.</p> <p>7 Q. Okay. Is it your understanding</p> <p>8 that --</p> <p>9 (Technical difficulties.)</p> <p>10 Q. My apologies. Again, I keep</p> <p>11 getting disconnected. Let's -- let me just</p> <p>12 withdraw that last question.</p> <p>13 So how is it that if Medtronic</p> <p>14 wanted to have a certain IFU for its product,</p> <p>15 the reservoir, and -- and that -- and that IFU</p> <p>16 is the one that Medtronic issued, how is it</p> <p>17 that Unomedical would have forced Medtronic to</p> <p>18 produce and provide a different IFU for its</p> <p>19 product than the one that Medtronic provided?</p> <p>20 A. According to Mr. Gharabli,</p> <p>21 Unomedical has been involved in the creation</p> <p>22 and working very closely with Medtronic on the</p> <p>23 IFU for the infusion set since the 501(k). It</p> <p>24 was --</p> <p>25 Q. For the infusion set --</p>

<p style="text-align: right;">Page 395</p> <p>1 W. VIGILANTE</p> <p>2 A. For the infusion set --</p> <p>3 Q. -- correct?</p> <p>4 A. -- but the infusion set is part of</p> <p>5 the system that's involved in this hazard.</p> <p>6 So if Unomedical said, "Hey, guys,</p> <p>7 we identified this hazard associated with this</p> <p>8 system, you need to make sure we're warning</p> <p>9 about it and we're suggest that you do it in</p> <p>10 the Paradigm IFU," and Medtronic says, "No, we</p> <p>11 don't care, we're not going to do it," then</p> <p>12 Unomedical has a couple choices. They can</p> <p>13 say, "Okay. Well, we're going to provide</p> <p>14 warning with our infusion set because that's</p> <p>15 half of the problem" or they can say, "I'm</p> <p>16 sorry, Medtronic, we're not going to</p> <p>17 manufacture this product for you and put it</p> <p>18 into the market because it's unreasonably</p> <p>19 dangerous and defective."</p> <p>20 So that seems to be the -- the two</p> <p>21 easiest choices that I can come up with at</p> <p>22 this point.</p> <p>23 Q. And at -- at the -- what -- what</p> <p>24 evidence do you have that at any time prior to</p> <p>25 2013 Unomedical was aware of the potential for</p>	<p style="text-align: right;">Page 396</p> <p>1 W. VIGILANTE</p> <p>2 users not to properly position the insulin</p> <p>3 vial below the reservoir and the connector</p> <p>4 when disconnecting the transfer guard and the</p> <p>5 reservoir from the insulin vial during the</p> <p>6 filling of the reservoir?</p> <p>7 A. So according to Mr. Gharabli, the</p> <p>8 corporation didn't recognize it until it</p> <p>9 became public in 2012, 2013, but according to</p> <p>10 their own records, they've been taking service</p> <p>11 calls related to this anomaly for a number of</p> <p>12 years, which means that they were aware of it</p> <p>13 even if they weren't aware of it at a</p> <p>14 corporate level.</p> <p>15 Q. So when you say "this anomaly,"</p> <p>16 your understanding is that Unomedical was</p> <p>17 aware for a number of years prior to 2013</p> <p>18 about this potential user error that can occur</p> <p>19 during the filling of the reservoir?</p> <p>20 A. Yeah, it's my understanding that</p> <p>21 when Unomedical went back and looked at</p> <p>22 their -- their calls, their service calls,</p> <p>23 they identified hundreds of these calls that</p> <p>24 were relevant or related to this anomaly over</p> <p>25 the years.</p>
<p style="text-align: right;">Page 397</p> <p>1 W. VIGILANTE</p> <p>2 Q. When you say "this anomaly,"</p> <p>3 you're talking about the temporary vent block</p> <p>4 that is the subject of the June 2013 letter to</p> <p>5 physicians and users and ultimately the</p> <p>6 subject of a voluntary recall?</p> <p>7 A. Of the prime fill anomaly.</p> <p>8 Q. All right. So --</p> <p>9 MR. SCHULTZ: Object to the form.</p> <p>10 Excuse me. I just want to interpose an</p> <p>11 objection. Object as not responsive.</p> <p>12 MS. MARTINEZ: I join.</p> <p>13 Q. Is it your understanding that the</p> <p>14 prime fill anomaly is the same thing as a</p> <p>15 temporary vent block?</p> <p>16 A. That's what it was all about, is</p> <p>17 the blockage of the vents on the P-cap.</p> <p>18 Q. So is the answer, yes, you believe</p> <p>19 that the temporary vent block is the same as</p> <p>20 the prime fill anomaly?</p> <p>21 A. Yes, the prime fill anomaly was</p> <p>22 caused by the blockage of the vents.</p> <p>23 Q. Other than what you've already</p> <p>24 stated, do you have any other criticisms of</p> <p>25 Unomedical with respect to the issue -- to the</p>	<p style="text-align: right;">Page 398</p> <p>1 W. VIGILANTE</p> <p>2 issues in this case?</p> <p>3 MR. SKLARSKY: Well, I'm just going</p> <p>4 to object to the form. You mean anything</p> <p>5 other than that's -- what he's already either</p> <p>6 testified to in a deposition --</p> <p>7 MS. MARTINEZ: Yes.</p> <p>8 MR. SKLARSKY: -- or in his report?</p> <p>9 MS. MARTINEZ: Other than what he's</p> <p>10 already testified to.</p> <p>11 MR. SKLARSKY: Well, all right. Let</p> <p>12 me just note my, you know, note my</p> <p>13 objection. It depends what questions were</p> <p>14 asked. He's issued a report that set forth</p> <p>15 the various opinions.</p> <p>16 A. Yeah, my opinions regarding</p> <p>17 Unomedical are -- are listed in my report and,</p> <p>18 you know, I stand by them.</p> <p>19 Q. Okay. We've covered some of them,</p> <p>20 and so I would like for you to point to your</p> <p>21 report what other criticisms of Unomedical you</p> <p>22 have.</p> <p>23 A. In my findings, Number 1,</p> <p>24 Number 3, Number 4, Number 5, Number 6,</p> <p>25 Number 9, Number 13, Number 14, Number 15,</p>

1 W. VIGILANTE  
2 Number 16, Number 17, Number 18.

3 Q. All right. So Number 1 says, "The  
4 unintended delivery of insulin resulting from  
5 the blockage of the P-cap connector vents  
6 created a hazard to users of the Paradigm  
7 infusion set and reservoir."

8 A. That's correct.

9 Q. All right. And the blockage of  
10 the P-cap connector vents, you're talking  
11 about insulin that gets on top of the  
12 reservoir if the user does not follow  
13 Medtronic's instructions on the filling of the  
14 reservoir; right?

15 A. That is one potential cause.

16 Q. All right. Well, let me ask you  
17 this: Is -- do you have any opinions or  
18 evidence in this case whatsoever that there  
19 was any other liquid or substance or  
20 contaminant, as I think you put it earlier,  
21 that was inside of the P-cap for Ms. Dennert's  
22 infusion sets that she used on the day of the  
23 incident?

24 MR. SKLARSKY: Just let me note an  
25 objection. I think we're really covering

1 W. VIGILANTE

2 ground that has, I gather, really been  
3 exhaustively reviewed at this point, so I  
4 think we're just --

5 MS. MARTINEZ: Actually, not. He --  
6 the answers that he gave -- you know, Mr.  
7 Schultz may have -- his question may have  
8 been broader, but Mr. Vigilante's answers  
9 were as to liquids or contaminants on top  
10 of the reservoir. I -- my question is  
11 different. I would like to know whether he  
12 has any evidence at all of any liquid,  
13 insulin, or contaminant that was inside  
14 Ms. Dennert's infusion set connector, her  
15 P-cap, and blocking the vents on the -- on  
16 the day of the incident.

17 A. Yes, I'm relying upon

18 Dr. Klimowicz.

19 And it's 1:35, 20 minutes beyond  
20 our agreed upon time frame, so I'm going to  
21 ask that we break for lunch 'cause I'm  
22 absolutely famished, and it doesn't sound like  
23 you're going to be done within the next five  
24 minutes.

25 Q. All right. There's a pending

1 W. VIGILANTE  
2 question, though, and I'd like an answer to my  
3 question.

4 Are you aware of any evidence that  
5 there was any liquid or other contaminants  
6 inside Ms. Dennert's infusion set P-cap,  
7 either set that she used the day before the  
8 incident or, you know, the evening of the  
9 incident or prior to the incident? Exclude  
10 insulin because I understand your opinion that  
11 based on what Mr. Klimowicz is testifying,  
12 that -- that you believe that somehow there  
13 was insulin inside a P-cap connector because  
14 it got on top of the reservoir.

15 My question is different and it  
16 is: Is there any evidence whatsoever that  
17 you've got that there was any liquid or  
18 contaminant other than insulin inside  
19 Ms. Dennert's infusion set P-cap on either  
20 infusion set that she used the day before she  
21 was found?

22 A. You changed your question.

23 Other than insulin, I do not.

24 Q. Okay.

25 A. And --

1 W. VIGILANTE

2 MS. MARTINEZ: We'll take a break.

3 THE WITNESS: Thank you.

4 MS. MARTINEZ: Thank you.

5 THE VIDEOGRAPHER: We are now going  
6 off the video record. That concludes DVD  
7 Number 2. The time is 13:38.

8 (A recess is held from 1:37 p.m. to  
9 2:36 p.m.)

10 THE VIDEOGRAPHER: Back on. This  
11 commences DVD Number 3, September 23rd,  
12 2016. The time, 14:37.

13 BY MS. MARTINEZ:

14 Q. Mr. Vigilante, before we broke for  
15 lunch we were talking about your finding  
16 Number 3 in your report; and basically it  
17 says, "Unomedical's failure to conduct any  
18 human factors testing," and we were exploring  
19 that.

20 Can you be more specific? Tell me  
21 what human factors testing and on what device  
22 Unomedical should have conducted.

23 A. Yeah, they -- they should have  
24 started with a task analysis on the infusion  
25 set system, which included its connection to

<p style="text-align: right;">Page 403</p> <p>1 W. VIGILANTE</p> <p>2 the Paradigm reservoir; and then they should</p> <p>3 have conducted usability studies much like</p> <p>4 Medtronic did or Mini-Med did.</p> <p>5 Q. Okay. So you're saying that</p> <p>6 Unomedical had a duty to conduct its own human</p> <p>7 factors testing and -- did you say feasibility</p> <p>8 studies?</p> <p>9 A. Usability studies.</p> <p>10 Q. Usability. Thank you.</p> <p>11 And your basis for saying that is</p> <p>12 what?</p> <p>13 A. It's your product. You're</p> <p>14 manufacturing the product. You're introducing</p> <p>15 the product into the stream of commerce.</p> <p>16 Q. When you say "the product," your</p> <p>17 talking about the infusion set?</p> <p>18 A. Yes.</p> <p>19 Q. All right. So can you describe</p> <p>20 for me, please, what that human factors and</p> <p>21 usability study that -- that Unomedical should</p> <p>22 have done, how should it have been performed?</p> <p>23 A. It should have been performed</p> <p>24 competently by a human factors professional.</p> <p>25 It should have started at the -- at the</p>	<p style="text-align: right;">Page 404</p> <p>1 W. VIGILANTE</p> <p>2 beginning of the design phase with determining</p> <p>3 requirements, determining what the system</p> <p>4 needed to do and not do, determining what</p> <p>5 potential steps were needed to use the product</p> <p>6 correctly, determining what kind of errors</p> <p>7 could be made, determining what kind of</p> <p>8 hazards are associated with those errors, what</p> <p>9 kind of information was needed to do the -- to</p> <p>10 use the product properly and safely, determine</p> <p>11 whether or not if it was going to include an</p> <p>12 IFU or other instructions and warnings,</p> <p>13 whether or not they were effective; and then</p> <p>14 validate that when they got it all together</p> <p>15 that people were using it and using it</p> <p>16 correctly.</p> <p>17 Q. Okay. And -- and you understand</p> <p>18 that -- or is that -- when you say "the</p> <p>19 product," you're talking about not only the</p> <p>20 infusion set, but you're talking about</p> <p>21 Medtronic's reservoir; correct?</p> <p>22 A. Including its connection to the</p> <p>23 reservoir, correct.</p> <p>24 Q. And do you understand that --</p> <p>25 that -- when you say at the point it was</p>
<p style="text-align: right;">Page 405</p> <p>1 W. VIGILANTE</p> <p>2 designed, that Unomedical did not design the</p> <p>3 reservoir, did not design the P-cap, so I'm</p> <p>4 confused when you say at the point it was</p> <p>5 designed.</p> <p>6 A. I'm sorry you're confused, but at</p> <p>7 some point Unomedical had to design the</p> <p>8 infusion set with the incorporation of that</p> <p>9 P-cap. That's part of the design process.</p> <p>10 I'm not sure what you're not understanding.</p> <p>11 Q. Okay. So you're talking about the</p> <p>12 infusion set, you're not talking about the</p> <p>13 reservoir?</p> <p>14 A. Yes.</p> <p>15 Q. And do you understand that</p> <p>16 Medtronic conducted usability and -- and human</p> <p>17 factors studies on both the P-cap and the</p> <p>18 reservoir; correct?</p> <p>19 A. They conducted it with the</p> <p>20 infusion set and the reservoir, but they only</p> <p>21 got to -- I think Task 10 was connecting</p> <p>22 the -- dropping the -- the reservoir into the</p> <p>23 pump. I don't think they ever looked at</p> <p>24 whether or not a person could -- could insert</p> <p>25 the cannula into the body.</p>	<p style="text-align: right;">Page 406</p> <p>1 W. VIGILANTE</p> <p>2 Q. I'm sorry. Is your answer, yes,</p> <p>3 Medtronic -- Medtronic conducted both human</p> <p>4 factors and usability studies on the</p> <p>5 reservoir, the P-cap, and the infusion set?</p> <p>6 A. They tested -- they did an</p> <p>7 assessment of the connection of the P -- of</p> <p>8 the reservoir to the infusion set.</p> <p>9 Q. Okay. But you're saying that</p> <p>10 Unomedical should have done their own human</p> <p>11 factors and usability studies and ignored</p> <p>12 Medtronic's?</p> <p>13 A. I didn't say that.</p> <p>14 Q. Okay. But you're saying that</p> <p>15 Unomedical should have conducted its own human</p> <p>16 factors and usability study on both the</p> <p>17 reservoir and the infusion set connection with</p> <p>18 the reservoir?</p> <p>19 A. What I'm saying is Unomedical was</p> <p>20 not aware of any human factors testing done on</p> <p>21 the product. They should have ensured it was</p> <p>22 done. If they were going to rely upon</p> <p>23 Medtronic's assessment, they should have made</p> <p>24 sure that Medtronic was doing it correctly.</p> <p>25 Q. Do you understand that</p>

<p style="text-align: right;">Page 407</p> <p>1 W. VIGILANTE</p> <p>2 Mr. Rabi Gharabli was deposed in his</p> <p>3 individual capacity?</p> <p>4 MR. SKLARSKY: I'm going to object</p> <p>5 to the form 'cause I just don't know what</p> <p>6 you mean by "individual capacity."</p> <p>7 MS. MARTINEZ: Okay.</p> <p>8 Q. Do you -- Mr. Vigilante, do you</p> <p>9 know the dist -- the difference between a --</p> <p>10 an employee of a company being deposed in</p> <p>11 their individual capacity versus their</p> <p>12 30(b)(6) or corporate representative capacity?</p> <p>13 A. Yes.</p> <p>14 Q. Do you, in fact, know what</p> <p>15 usability study, what risk analysis, what</p> <p>16 human factors information Unomedical had in</p> <p>17 its possession at or around the time that it</p> <p>18 submitted the 510(k) to the FDA?</p> <p>19 MR. SKLARSKY: Objection to the</p> <p>20 form. Go ahead.</p> <p>21 A. According to Mr. Gharabli, who was</p> <p>22 involved in the submission of the 501(k), he</p> <p>23 does not recall any human factors testing to</p> <p>24 determine proper use of the infusion set. He</p> <p>25 does not recall any human factors studies or</p>	<p style="text-align: right;">Page 408</p> <p>1 W. VIGILANTE</p> <p>2 analysis involving the Paradigm Quick-set</p> <p>3 infusion set.</p> <p>4 Q. Okay. And -- and all that you're</p> <p>5 relying on is Mr. Gharabli's testimony,</p> <p>6 correct, you don't have testimony from anyone</p> <p>7 else at Unomedical?</p> <p>8 A. That's correct.</p> <p>9 Q. Okay. And, again, just to be</p> <p>10 sure, what -- what you put -- let me -- let me</p> <p>11 go to your Finding Number 4, which says, "Had</p> <p>12 Medtronic and Unomedical performed an adequate</p> <p>13 human factors analysis of their reservoir,</p> <p>14 infusion set, and P-cap connector" -- and,</p> <p>15 again, understanding that the reservoir was</p> <p>16 not Unomedical's product -- "they would have</p> <p>17 identified the potential for users to remove</p> <p>18 the reservoir while it was upright under the</p> <p>19 insulin vial, insulin to contaminate the P-cap</p> <p>20 membrane, and the hazard created by the</p> <p>21 blockage of the P-cap connector vents."</p> <p>22 Is that what you would have</p> <p>23 expected for the human factors testing and the</p> <p>24 usability testing that you expected Unomedical</p> <p>25 to conduct, is that what you would have</p>
<p style="text-align: right;">Page 409</p> <p>1 W. VIGILANTE</p> <p>2 expected Unomedical to test for or to find?</p> <p>3 A. I would have expected that if</p> <p>4 Unomedical performed adequate human factors</p> <p>5 evaluation or relied upon an adequate human</p> <p>6 factors evaluation by Medtronic, they would</p> <p>7 have identified it.</p> <p>8 Q. And, again, you're -- you --</p> <p>9 you're not testifying as a regulatory expert,</p> <p>10 correct, as an FDA expert?</p> <p>11 MR. SKLARSKY: Objection, to the --</p> <p>12 to the form of the question. He -- you</p> <p>13 know, it's clear --</p> <p>14 MS. MARTINEZ: I'm sorry. I didn't</p> <p>15 hear the --</p> <p>16 MR. SKLARSKY: I'm objecting to the</p> <p>17 -- I'm objecting to the form of the</p> <p>18 question.</p> <p>19 MS. MARTINEZ: Thank you.</p> <p>20 Q. Sir, you're not an FDA expert;</p> <p>21 correct?</p> <p>22 A. Depends on the topic.</p> <p>23 Q. I'm sorry?</p> <p>24 A. Depends on the topic.</p> <p>25 Q. What topics are you -- do you</p>	<p style="text-align: right;">Page 410</p> <p>1 W. VIGILANTE</p> <p>2 consider yourself an FDA expert, with respect</p> <p>3 to which topics?</p> <p>4 A. Well, maybe I can short circuit</p> <p>5 this for you because we went over this</p> <p>6 in-depth in the first deposition so I'm not</p> <p>7 sure why you're re-asking it today.</p> <p>8 I'm not holding myself out as an</p> <p>9 FDA expert with respect to matters in this</p> <p>10 case. I'm leaving those questions regarding</p> <p>11 the regulations and the approvals and the</p> <p>12 processes associated with it to Dr. Klimowicz.</p> <p>13 Q. Okay. And my question was more,</p> <p>14 just to be clear, that the hazard that you are</p> <p>15 contemplating in -- in your report and that</p> <p>16 you would have expected Unomedical to discover</p> <p>17 as a result of what you believe should have</p> <p>18 been proper human factors testing is the</p> <p>19 hazard of not having the insulin vial below</p> <p>20 the reservoir and the -- and the transfer</p> <p>21 guard in the process of disconnection;</p> <p>22 correct?</p> <p>23 MR. SKLARSKY: Object. Objection to</p> <p>24 the form. You know, it's a partial</p> <p>25 representation of his testimony, but it's</p>

Page 411

1 W. VIGILANTE

2 also been asked and answered ad nauseam  
3 from both the prior dep as well as today.

4 Q. Go ahead.

5 A. Yeah, my testimony is, is that  
6 they would have been aware of the over- or  
7 under-dispensing of insulin hazard associated  
8 with the blockage of the P-cap vents had they  
9 done adequate testing. They would have been  
10 aware of it, that the IFU, the way it was  
11 written and the steps in which were required  
12 to prevent insulin specifically from  
13 contacting the P-cap vents, would not have  
14 been -- were not adequate.

15 Q. Okay. And when you say "the IFU,"  
16 you're talking about Medtronic's reservoir  
17 IFU; correct?

18 A. Sure.

19 Q. So just to be clear, your opinion  
20 is that in addition to any usability, human  
21 factors, or risk analysis that Medtronic  
22 conducted with respect to the reservoir, the  
23 infusion set and the P-cap as a system, that  
24 Unomedical had a duty to conduct its own?

25 MR. SKLARSKY: It's been asked and

Page 412

1 W. VIGILANTE

2 answered, and I object to the form in  
3 terms of --

4 Q. Go ahead.

5 MR. SKLARSKY: -- some of the  
6 language you put in there.

7 A. That's not what I testified to.

8 Q. Well, now I'm really confused  
9 then. Can you -- can you please --  
10 (Technical difficulties.)

11 MR. SKLARSKY: This has been  
12 covered. I think it's really been fully  
13 explored. I don't know how many times you  
14 can keep going over the same -- same  
15 ground.

16 MR. SCHULTZ: Oh, boy.

17 MS. MARTINEZ: I'm very -- hello?  
18 Can you hear me?

19 MR. SKLARSKY: Yeah.

20 MR. SCHULTZ: We hear you.

21 MS. MARTINEZ: I'm sorry. I --  
22 it disconnected again. Never again through  
23 Skype. I apologize.

24 Q. Did you an -- were you starting to  
25 answer my last question, Mr. Vigilante?

Page 413

1 W. VIGILANTE

2 MR. SKLARSKY: Well, I had an  
3 objection that I had placed on the record.

4 Q. Okay.

5 A. And you never asked a question.  
6 You made a statement and then said "please."

7 Q. No. I -- I -- I asked a question.  
8 I said is it your testimony that despite any  
9 risk analysis or human factors analysis or  
10 usability study that Medtronic conducted, that  
11 Unomedical had an independent duty to conduct  
12 its own risk analysis and human factors and  
13 usability study that involved Medtronic's  
14 reservoir and the infusion set.

15 MR. SKLARSKY: He's already -- he's  
16 already asked that. Let's go on to another  
17 question.

18 MS. MARTINEZ: No, I -- he said --

19 MR. SKLARSKY: No, I'm -- no, I'm --  
20 (Reporter clarification -  
21 simultaneous speaking.)

22 MR. SKLARSKY: No. There is a  
23 limit, okay, and we've reached that at this  
24 point, so ask another question.

25 MS. MARTINEZ: No, I'm not -- I'm

Page 414

1 W. VIGILANTE

2 not going to ask -- because I asked that  
3 question and he said, no, that was not my  
4 testimony, and I'm trying to clarify what  
5 is his testimony.

6 MR. SKLARSKY: About what?

7 MS. MARTINEZ: About what I just  
8 asked, whether Unomedical had an  
9 independent duty to conduct a usability  
10 study, a human factors study, and a risk  
11 analysis independent of what Medtronic may  
12 have done with respect to the reservoir,  
13 the infusion set, the P-cap.

14 MR. SKLARSKY: All right. He's  
15 answered it, but I'll allow him to once  
16 again if he understands the question, to --  
17 to respond.

18 A. That wasn't my testimony.

19 Q. What is your testimony, sir?

20 A. They had a responsibility to  
21 ensure it was done, whether they did it  
22 independently or they did it in conjunction or  
23 they relied upon Medtronic. They had a  
24 responsibility to make sure it was done and  
25 that it was done properly.

<p style="text-align: right;">Page 415</p> <p>1 W. VIGILANTE</p> <p>2 Q. Okay. Thank you for that</p> <p>3 clarification.</p> <p>4 So if, in fact, Unomedic --</p> <p>5 Medtronic conducted a usability study and --</p> <p>6 and a human factors study and a risk analysis,</p> <p>7 as I understand your testimony, Unomedical did</p> <p>8 not have a duty to independently conduct any</p> <p>9 of those on its own, but rather, according to</p> <p>10 your view, had a duty to make sure that what</p> <p>11 was done by Medtronic was proper as, you</p> <p>12 know -- and by "proper," I mean as you view it</p> <p>13 properly; correct?</p> <p>14 MR. SKLARSKY: Well, that -- I</p> <p>15 object, again, to the characterization</p> <p>16 because that's not completely what he said.</p> <p>17 Okay.</p> <p>18 A. So --</p> <p>19 MR. SKLARSKY: Go ahead.</p> <p>20 A. -- for maybe multiple times, if</p> <p>21 they were going to rely upon Medtronic to do</p> <p>22 it, they needed to make sure that it was done</p> <p>23 in an adequate fashion.</p> <p>24 Q. Okay.</p> <p>25 A. And if Medtronic wasn't going to</p>	<p style="text-align: right;">Page 416</p> <p>1 W. VIGILANTE</p> <p>2 do it in an adequate fashion, they needed to</p> <p>3 make other arrangements, whether it was doing</p> <p>4 it themselves or having Medtronic redo it or</p> <p>5 hiring a third party to do it for them.</p> <p>6 Q. Okay. Thank you.</p> <p>7 Mr. Vigilante, do you know which</p> <p>8 hand is Rachel Dennert's dominant hand?</p> <p>9 A. I don't know that I know that</p> <p>10 offhand.</p> <p>11 Q. Okay. Would it matter to your</p> <p>12 analysis whether she -- her dominant hand was</p> <p>13 her left or her right?</p> <p>14 A. No.</p> <p>15 MR. SKLARSKY: Once, again, I -- I</p> <p>16 may be wrong, I thought this was also</p> <p>17 covered in the first day of depositions.</p> <p>18 MS. MARTINEZ: Not this specific</p> <p>19 question.</p> <p>20 MR. SKLARSKY: No, I -- it was, but</p> <p>21 go ahead.</p> <p>22 Q. So, sir, it would not matter to</p> <p>23 your analysis or your opinions whether</p> <p>24 Rachel's dominant hand was her right or her</p> <p>25 left?</p>
<p style="text-align: right;">Page 417</p> <p>1 W. VIGILANTE</p> <p>2 A. That's correct.</p> <p>3 Q. Let me ask you this: Can -- can</p> <p>4 instructions that are proper in your view be</p> <p>5 proper instructions even if the warnings given</p> <p>6 are, in your view, not proper?</p> <p>7 MR. SKLARSKY: Excuse me?</p> <p>8 A. Yeah, so you can have instructions</p> <p>9 that are fine that don't have a -- a warning</p> <p>10 in them, but if your instructions include a</p> <p>11 warning, then the warning better be adequate,</p> <p>12 otherwise, the instructions are not very good.</p> <p>13 Q. All right. So you're saying that</p> <p>14 you can have instructions that are adequate</p> <p>15 and appropriate in your view, that don't</p> <p>16 necessarily include warnings?</p> <p>17 A. Yeah, not all instructions have</p> <p>18 warnings. Not all instructions need warnings.</p> <p>19 If you don't need a warning, I wouldn't expect</p> <p>20 them to have a warning.</p> <p>21 Q. Okay. In terms of using devices</p> <p>22 and how people use devices, would you agree</p> <p>23 with me that what is convenient for one user</p> <p>24 may not be a convenient way for another user?</p> <p>25 A. Sure.</p>	<p style="text-align: right;">Page 418</p> <p>1 W. VIGILANTE</p> <p>2 Q. I think I may just have one last</p> <p>3 question.</p> <p>4 Do you have any evidence</p> <p>5 whatsoever that on -- on the day she used the</p> <p>6 infusion sets -- let -- let me strike that.</p> <p>7 Do you have any evidence</p> <p>8 whatsoever that when Ms. Dennert filled her</p> <p>9 reservoir on the evening before she was found,</p> <p>10 that when she disconnected the transfer guard</p> <p>11 and the reservoir from the insulin vial, that</p> <p>12 the insulin vial was anywhere other than</p> <p>13 underneath and below the reservoir and the</p> <p>14 transfer guard?</p> <p>15 A. Yeah, the only evidence I'm</p> <p>16 relying upon is the fact that she experienced</p> <p>17 a prime fill anomaly and that's the way it's</p> <p>18 caused, and we know that there were not</p> <p>19 adequate instructions and warnings to alert</p> <p>20 her, and that it was natural to do it in that</p> <p>21 fashion, and, in fact, many people were doing</p> <p>22 it in such a fashion, and a direct result of</p> <p>23 that is potential contamination of the</p> <p>24 reservoir and P-cap vents leading to the prime</p> <p>25 fill anomaly.</p>

<p style="text-align: right;">Page 419</p> <p>1 W. VIGILANTE</p> <p>2 Q. Okay. And I think we covered</p> <p>3 that. So you do not have any evidence other</p> <p>4 than what you just said to us of anyone having</p> <p>5 seen Rachel Dennert fill her reservoir that</p> <p>6 evening and noticing that when she</p> <p>7 disconnected the reservoir from the insulin</p> <p>8 vial, that the reservoir [sic] was any place</p> <p>9 other than below the transfer guard and the</p> <p>10 reservoir?</p> <p>11 A. Yeah, I'm not aware of any</p> <p>12 eyewitness testimony.</p> <p>13 Q. Do you have any testimony from any</p> <p>14 witness or any other evidence other than what</p> <p>15 you've already talked to us about that at any</p> <p>16 time during -- any time that Rachel filled her</p> <p>17 reservoir that the insulin vial was anywhere</p> <p>18 other than below the transfer guard and the</p> <p>19 reservoir when she disconnected the insulin</p> <p>20 vial from those two items?</p> <p>21 A. Yeah, that was never asked to</p> <p>22 Rachel's mom, so I don't have that</p> <p>23 information.</p> <p>24 Q. I'm sorry. Can you repeat that?</p> <p>25 I didn't hear.</p>	<p style="text-align: right;">Page 420</p> <p>1 W. VIGILANTE</p> <p>2 A. It was never asked to</p> <p>3 Ms. Dennert's mom, so I don't have that</p> <p>4 information.</p> <p>5 Q. Do you have any such information</p> <p>6 from any source that is not necessarily Nancy</p> <p>7 Dennert's testimony?</p> <p>8 MR. SKLARSKY: I'll object to the</p> <p>9 form. If you understand it, you can try to</p> <p>10 answer it.</p> <p>11 A. No, I mean, we've already been</p> <p>12 over this a dozen times. The -- the -- she</p> <p>13 suffered a prime fill anomaly and it's</p> <p>14 associated with the phenomenon of removing the</p> <p>15 reservoir from under the insulin vial.</p> <p>16 Medtronic has shown that people have been</p> <p>17 doing it. Unomedical/Medtronic have records</p> <p>18 of -- of this issue happening over time.</p> <p>19 We've seen the YouTube videos. We've got the</p> <p>20 letters and the notices stating that this is</p> <p>21 what happens. So, you know, that's what I'm</p> <p>22 relying upon, and plus the -- the analysis of</p> <p>23 Dr. Klimowicz.</p> <p>24 Q. So you -- you have -- other than</p> <p>25 what you just said, you have no direct</p>
<p style="text-align: right;">Page 421</p> <p>1 W. VIGILANTE</p> <p>2 evidence or testimony that at any time since</p> <p>3 Ms. Dennert started using the infusion pump</p> <p>4 and the infusion set, that when she</p> <p>5 disconnected the reservoir and the transfer</p> <p>6 guard from her insulin vial, that the insulin</p> <p>7 vial was anywhere other than below the</p> <p>8 transfer guard and the reservoir?</p> <p>9 A. Yeah, I'm sorry. The only two</p> <p>10 people that would know that, would be aware of</p> <p>11 that are Rachel Dennert, and she doesn't</p> <p>12 recall, my understanding, and her mom, and her</p> <p>13 mom wasn't asked that. So that's all I have</p> <p>14 with respect to eyewitnesses to -- as to what</p> <p>15 Ms. Dennert did and didn't do prior to her</p> <p>16 injury.</p> <p>17 MS. MARTINEZ: Okay. I'm going to</p> <p>18 pass the witness for -- for right now, and</p> <p>19 I may have a couple of follow-up things,</p> <p>20 but I'll just wait and see. Thank you.</p> <p>21 THE WITNESS: You're welcome.</p> <p>22 EXAMINATION</p> <p>23 BY MR. SCHULTZ:</p> <p>24 Q. I only have one question,</p> <p>25 Mr. Vigilante, and I can guarantee it hasn't</p>	<p style="text-align: right;">Page 422</p> <p>1 W. VIGILANTE</p> <p>2 been asked before.</p> <p>3 When a manufacturer is conducting</p> <p>4 a usability study, is there a conventional --</p> <p>5 well, is there a convention as to how many</p> <p>6 different users that study should be involved</p> <p>7 or is there a range?</p> <p>8 A. I think the minimum of five is</p> <p>9 fine and then after you get past maybe 20 you</p> <p>10 run into expending more resources than -- than</p> <p>11 information you're getting, so it doesn't</p> <p>12 become cost effective. So there's nothing</p> <p>13 wrong with the 10 that were used in the two</p> <p>14 usability studies as far as numbers go for the</p> <p>15 usability study that Medtronic done. It was</p> <p>16 a -- more of an issue with the -- the people</p> <p>17 they selected for the study.</p> <p>18 Q. Right. I -- I understand that</p> <p>19 aspect of your opinion. I just want to make</p> <p>20 sure there's -- in terms of the number, is the</p> <p>21 number ten is not objectionable?</p> <p>22 A. Yeah, for a study like that I</p> <p>23 don't -- I don't see the number being an</p> <p>24 issue.</p> <p>25 Q. And you're not aware of studies</p>

<p style="text-align: right;">Page 423</p> <p>1 W. VIGILANTE</p> <p>2 that used, for example, 100 or 500? You're</p> <p>3 not saying that's necessary.</p> <p>4 A. For the type of study they were</p> <p>5 doing, I don't think it's necessary.</p> <p>6 MR. SCHULTZ: Okay. That's --</p> <p>7 that's all I have. Thank you.</p> <p>8 THE WITNESS: You're welcome.</p> <p>9 EXAMINATION</p> <p>10 BY MS. MARTINEZ:</p> <p>11 Q. I've got one more question.</p> <p>12 Mr. Vigilante, do you -- do you</p> <p>13 have an opinion based on any studies or other</p> <p>14 sources as to how many times a user will</p> <p>15 review or read an IFU for a device before</p> <p>16 never again reading or relying upon that IFU?</p> <p>17 MR. SKLARSKY: I'm going to object</p> <p>18 to the form only because I'm -- the way,</p> <p>19 and you may have cut out a little bit so I</p> <p>20 may have not heard the whole thing, but</p> <p>21 I'll see if our witness understands it.</p> <p>22 A. Yeah, I mean, I don't -- I have</p> <p>23 never seen a study that says X. So it's going</p> <p>24 to be dependent upon the complexity of the</p> <p>25 tasks, whether or not the person is familiar</p>	<p style="text-align: right;">Page 424</p> <p>1 W. VIGILANTE</p> <p>2 with the task or similar tasks, and it's going</p> <p>3 to have a little bit to do with the person's</p> <p>4 abilities -- innate abilities, memory,</p> <p>5 confidence, and so forth. So it's multiple</p> <p>6 and it's variable, but I've never seen a -- a</p> <p>7 specific number given.</p> <p>8 Q. Okay. Do you have an opinion in</p> <p>9 this case as to how many times Ms. Dennert</p> <p>10 would have used and read and relied upon the</p> <p>11 IFU for the reservoir before she didn't need</p> <p>12 it anymore and just did it without referring</p> <p>13 to or relying upon the IFU?</p> <p>14 A. According to Mrs. Dennert's mom,</p> <p>15 she used them every time that she did the</p> <p>16 task. She was a relatively new user, so</p> <p>17 certainly as she became more and more</p> <p>18 experienced with it, her use of the IFUs</p> <p>19 would -- would decrease, that's what you would</p> <p>20 expect.</p> <p>21 Q. Ms. Dennert had -- we -- we've</p> <p>22 discussed a number of different sources of</p> <p>23 information that Ms. Dennert had available to</p> <p>24 her --</p> <p>25 (Technical difficulties.)</p>
<p style="text-align: right;">Page 425</p> <p>1 W. VIGILANTE</p> <p>2 A. We can't -- we can't hear you.</p> <p>3 MR. SKLARSKY: We're back to the IT</p> <p>4 person.</p> <p>5 A. All right. We're...</p> <p>6 Q. Okay. This will all be over</p> <p>7 soon. I apologize. Cut out again.</p> <p>8 MR. SKLARSKY: Thank God.</p> <p>9 Q. So my question was: We've</p> <p>10 discussed a number of different sources of</p> <p>11 information that Ms. Dennert had with respect</p> <p>12 to how to use her insulin pump and</p> <p>13 specifically how to fill her reservoir and</p> <p>14 connect her infusion set, including the</p> <p>15 training she received from the CDE and also</p> <p>16 any written materials she may have been</p> <p>17 provided.</p> <p>18 Do you have any opinions on which</p> <p>19 sources of information are more often relied</p> <p>20 upon by users of devices and then also</p> <p>21 specifically as to Ms. Dennert?</p> <p>22 MR. SKLARSKY: Just note my</p> <p>23 objection 'cause it's pretty compound.</p> <p>24 You've put in an awful lot of different</p> <p>25 aspects of it, but...</p>	<p style="text-align: right;">Page 426</p> <p>1 W. VIGILANTE</p> <p>2 A. So you had some predicates that I</p> <p>3 can't agree with, but I can tell you that the</p> <p>4 information and training, as I mentioned</p> <p>5 earlier in the deposition, needs to be</p> <p>6 reinforced over time, and warnings and</p> <p>7 instructions are typically -- are specifically</p> <p>8 in this case, how they reinforced them over</p> <p>9 time. So training is good, but if it's not</p> <p>10 reinforced over time, people have a tendency</p> <p>11 to forget. That's a limitation of training.</p> <p>12 And they can -- as they forget, they can</p> <p>13 regress to previous behaviors or they can</p> <p>14 regress to different behaviors if they have no</p> <p>15 prior experience.</p> <p>16 So the warnings and instructions</p> <p>17 are important after the initial training to</p> <p>18 reinforce and to provide consistent --</p> <p>19 consistent information so that you know and</p> <p>20 are doing the task right.</p> <p>21 Q. What is your opinion as to how</p> <p>22 soon after training such information that</p> <p>23 reinforces the training needs to be provided?</p> <p>24 Is it within a month? Is it two? Is it</p> <p>25 three?</p>

1 W. VIGILANTE  
2 A. Well, Medtronic and Unomedical is  
3 providing it with -- with each set of infusion  
4 sets and Paradigm -- or excuse me, reservoirs.  
5 So that's a good thing. You're providing them  
6 with the IFU, so every time they go to use the  
7 product it's there to reinforce their  
8 training. Every time they get a new set, it's  
9 there again to reinforce the training, whether  
10 it's from the CDU, or the CDE or the online  
11 videos or what have you.  
12 MS. MARTINEZ: Okay. All right.  
13 All right. I don't have any further  
14 questions. Thank you very much.  
15 THE WITNESS: Thank you.  
16 MR. SCHULTZ: I have no further  
17 questions, Mr. Vigilante. Thank you.  
18 THE WITNESS: Thank you.  
19 MR. SKLARSKY: Thanks. Everybody,  
20 have a good -- have a good weekend.  
21 MS. MARTINEZ: Thanks. You too.  
22 MR. SCHULTZ: Before we disconnect,  
23 Madame Court Reporter --  
24 COURT REPORTER: Yes.  
25 MR. SCHULTZ: -- we'll take an

1 W. VIGILANTE  
2 expedited transcript, please.  
3 MS. MARTINEZ: Same here.  
4 COURT REPORTER: Okay. Do you know  
5 what day you want it by?  
6 MR. SCHULTZ: As soon as you can get  
7 it to us.  
8 COURT REPORTER: Okay.  
9 MS. MARTINEZ: Thank you.  
10 MR. SCHULTZ: I think we can --  
11 COURT REPORTER: Do you mean Monday  
12 by that? Do you mean Monday by that?  
13 (Transcript continued on next page  
14 to allow for Jurat.)  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

1 W. VIGILANTE  
2 MR. SKLARSKY: Wait, wait, wait.  
3 MR. SCHULTZ: Monday would be great.  
4 COURT REPORTER: Same with you?  
5 MS. MARTINEZ: Yes.  
6 COURT REPORTER: Okay.  
7 MS. MARTINEZ: Thank you.  
8 MR. SCHULTZ: Thank you.  
9 MR. SKLARSKY: All right. So long.  
10 Take care.  
11 THE VIDEOGRAPHER: That now  
12 concludes this deposition and DVD Number 3.  
13 The time is 15:10.  
14 (Time noted is 3:10 p.m.)  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

William J. Vigilante, Jr., PhD, CPE

Subscribed and sworn to  
before me this \_\_\_\_\_ day  
of \_\_\_\_\_, 2016.

1	W. VIGILANTE	
2	I N D E X	
3	WITNESS	PAGE
4	William J. Vigilante, Jr., Ph.D.	
5	BY MR. SCHULTZ	273
6	BY MS. MARTINEZ	358
7	BY MR. SCHULTZ	421
8	BY MS. MARTINEZ	423
9	E X H I B I T S	
10	NUMBER DESCRIPTION PAGE	
11	Exhibit Vigilante-18, multipage document	301
12	entitled Paradigm 522 and 722 Insulin	
13	Pumps User Guide bearing Bates Numbers	
14	MDT000073RD through MDT000332RD	
15	Exhibit Vigilante-19, CDROM entitled	319
16	Rachel Dennert vs. Medtronic	
17	Instructional CD-ROM MDT071234RD,	
18	Exhibit Vigilante-20, multipage document	323
19	entitled Self-Help Storyboard Filling the	
20	Reservoir and Priming bearing Bates	
21	Numbers MDT071290RD through MDT071322RD	
22	PREVIOUSLY MARKED EXHIBITS	
23	NUMBER DESCRIPTION PAGE	
24	Exhibit Vigilante-11, letter dated June	282
25	16, 2016 addressed to Kevin Haverty, Esq.	
	Exhibit Vigilante-10, Report of William	289
	J. Vigilante, Jr., PhD, CPE dated April	
	19, 2016	
	Exhibit Vigilante-17, document entitled	324
	Medtronic MiniMed Paradigm Reservoir Rx	
	Only	

Page 431

Page 432

CERTIFICATE  
COMMONWEALTH OF PENNSYLVANIA )  
 ) ss:

COUNTY OF PHILADELPHIA )  
I, Debra Sapio Lyons, a Registered  
Diplomat Reporter, a Certified Realtime Reporter,  
a Certified Realtime Captioner, an Approved  
Reporter of the United States District Court for  
the Eastern District of Pennsylvania, a Certified  
Court Reporter for the State of New Jersey; and  
Notary Public within and for the States of New  
Jersey, New York and the Commonwealth of  
Pennsylvania do hereby certify:

That William J. Vigilante, Jr., PhD,  
CPE, the witness whose deposition is hereinbefore  
set forth, was duly sworn by me and that such  
deposition is a true record of the testimony  
given by such witness, to the best of my ability  
and thereafter reduced to typewriting under my  
direction.

I further certify that I am not related to any of the parties to this action by blood or marriage and that I am in no way interested in the outcome of the matter.

In witness whereof, I have hereunto set  
my hand this 26th day of September, 2016.

DEBRA SAPIO LYONS  
CRR, RDR, CRC, CCR, CPE

## ERRATA SHEET

Case Name:

Deposition Date:

Deponent:

Pg.	No.	Now Reads	Should Read	Reason
-----	-----	-----------	-------------	--------

[illegible]

Signature of Deponent

SUBSCRIBED AND SWORN BEFORE ME

THIS \_\_\_\_ DAY OF \_\_\_\_\_, 2016.

(Notary Public) MY COMMISSION EXPIRES:\_\_\_\_\_

<b>A</b>	356:25 357:3	<b>ambiguous (2)</b>	425:7	<b>assemble (1)</b>
<b>a.m (4)</b>	371:25 376:20,24	306:10 340:15	<b>apparently (1)</b>	375:13
270:16 277:12,13	376:25 384:5 386:8	<b>analysis (28)</b>	384:18	<b>assembly (1)</b>
334:24	387:8,16,19,21	274:21 275:3 290:15	<b>APPEARANCES (1)</b>	369:24
<b>A/S (2)</b>	388:18 391:9	298:2 309:3 341:23	272:1	<b>assess (1)</b>
270:11 272:17	408:12 409:4,5	368:17 391:3,4,12	<b>appeared (4)</b>	337:23
<b>abilities (2)</b>	411:9,14 415:23	391:22 392:2,18,20	361:2,2,3,11	<b>assessed (2)</b>
424:4,4	416:2 417:11,14	393:12 402:24	<b>append (1)</b>	276:16 284:5
<b>ability (1)</b>	418:19	407:15 408:2,13	370:25	<b>assessment (5)</b>
431:13	<b>adequately (2)</b>	411:21 413:9,9,12	<b>appendix (2)</b>	280:19 281:23 343:6
<b>able (1)</b>	348:2 388:24	414:11 415:6	350:7,12	406:7,23
332:5	<b>advertisements (1)</b>	416:12,23 420:22	<b>appreciate (2)</b>	<b>associated (18)</b>
<b>absence (4)</b>	354:21	<b>analyze (1)</b>	315:13 316:18	290:18 294:21,22
339:9,20 340:11	<b>advisory (1)</b>	305:13	<b>appreciated (1)</b>	296:25 297:13
344:7	337:3	<b>and/or (1)</b>	316:8	299:5 311:2 314:19
<b>absolutely (2)</b>	<b>agree (22)</b>	380:23	<b>appropriate (4)</b>	317:9,17 349:2
289:2 400:22	279:23,25 288:3,3	<b>animation (2)</b>	280:17 310:5 311:15	388:15,16 395:7
<b>accepted (1)</b>	295:7 298:4 304:12	321:3,4	417:15	404:8 410:12 411:7
318:25	304:21 305:3	<b>anomalies (1)</b>	<b>approvals (1)</b>	420:14
<b>accompanied (4)</b>	308:18 326:25	297:18	410:11	<b>assume (4)</b>
321:25 328:21 336:22	327:11,16 337:18	<b>anomaly (28)</b>	<b>Approved (2)</b>	307:12 367:15 381:20
378:9	339:5,15 340:10,21	290:18 292:15 297:2	271:14 431:7	382:11
<b>acknowledged (2)</b>	353:11 390:2	333:16 346:9	<b>approximately (2)</b>	<b>assuming (6)</b>
312:4 375:7	417:22 426:3	348:13 349:9	295:17 369:22	274:9 296:4,16 310:4
<b>acquire (1)</b>	<b>agreed (1)</b>	371:22 372:4	<b>April (3)</b>	311:18 387:22
353:4	400:20	376:15 377:16	289:16 336:17 430:20	<b>assumptions (1)</b>
<b>acronym (1)</b>	<b>ahead (10)</b>	378:13 388:3 389:3	<b>area (1)</b>	287:10
312:18	281:19 298:9 306:3	389:7 390:10,16	344:16	<b>Atlanta (1)</b>
<b>action (3)</b>	318:19 376:10	396:11,15,24 397:2	<b>argue (1)</b>	272:16
270:7 361:4 431:15	407:20 411:4 412:4	397:7,14,20,21	286:21	<b>attach (1)</b>
<b>actions (1)</b>	415:19 416:21	418:17,25 420:13	<b>arguing (1)</b>	390:24
279:6	<b>air (3)</b>	<b>answer (24)</b>	286:18	<b>attached (1)</b>
<b>actively (1)</b>	278:14 358:21,22	280:12 281:15 285:16	<b>arrangements (1)</b>	363:23
328:25	<b>Alan (2)</b>	288:4 289:5 296:12	416:3	<b>attaching (1)</b>
<b>actors (1)</b>	272:2 301:11	308:25 311:11	<b>artful (1)</b>	371:19
320:25	<b>alert (11)</b>	316:11 340:2	353:24	<b>attempts (1)</b>
<b>actual (3)</b>	288:22,24 292:7	345:18 357:4	<b>articles (1)</b>	280:14
325:11,21 328:21	294:24 297:6 341:2	359:21,25 371:2	352:21	<b>attention (4)</b>
<b>ad (1)</b>	348:8,20 384:8	385:24,25 386:4,7	<b>aside (1)</b>	282:15 294:23 358:17
411:2	386:11 418:19	397:18 401:2 406:2	279:24	376:17
<b>addition (1)</b>	<b>alerted (1)</b>	412:25 420:10	<b>asked (16)</b>	<b>Attorneys (3)</b>
411:20	309:10	<b>answered (5)</b>	281:16 317:20 344:12	272:4,10,17
<b>additional (3)</b>	<b>alerts (2)</b>	291:24 357:14 411:2	381:12 398:14	<b>attribute (2)</b>
273:25 322:21 329:9	363:19 366:5	412:2 414:15	411:2,25 413:5,7,16	277:25 278:7
<b>address (1)</b>	<b>ALFE (1)</b>	<b>answers (2)</b>	414:2,8 419:21	<b>August (6)</b>
376:14	272:21	400:6,8	420:2 421:13 422:2	295:18 298:6 307:22
<b>addressed (2)</b>	<b>alive (1)</b>	<b>anybody (1)</b>	<b>asking (12)</b>	331:2 335:19
282:9 430:19	320:25	336:8	280:11 281:15 291:18	340:10
<b>adequacy (1)</b>	<b>Alliance (1)</b>	<b>anymore (2)</b>	293:21 305:13	<b>avail (1)</b>
357:8	272:15	350:13 424:12	312:8 329:12	393:25
<b>adequate (38)</b>	<b>allow (3)</b>	<b>apart (1)</b>	344:24 352:12,13	<b>availability (1)</b>
279:12 281:2 290:4	341:2 414:15 428:14	383:23	355:12 380:11	394:2
291:11 292:6 295:9	<b>allowed (1)</b>	<b>apologies (2)</b>	<b>aspect (3)</b>	<b>available (3)</b>
309:4 311:15,20	293:12	393:6 394:10	283:22 376:8 422:19	350:12 382:13 424:23
316:15 319:9	<b>allowing (1)</b>	<b>apologize (4)</b>	<b>aspects (1)</b>	<b>avoid (8)</b>
337:18,24 354:4	287:9	374:6 389:12 412:23	425:25	295:2 312:2 346:14

346:25 348:21,22 384:9 386:12 <b>aware (46)</b> 276:9 277:16 278:25 282:23 307:6,20 314:13,16 316:25 317:2,21,25 318:2 318:10,22 321:6 334:10 338:5 341:7 342:23 350:10,14 352:20,24 363:13 369:8,17,21 391:19 392:2,22,25 393:9 393:14,15 395:25 396:12,13,17 401:4 406:20 411:6,10 419:11 421:10 422:25 <b>awful (2)</b> 308:6 425:24 <hr/> <p style="text-align: center;"><b>B</b></p> <hr/> <b>B (1)</b> 430:7 <b>back (23)</b> 274:19 277:14 283:5 293:23 297:19 299:21 308:6,11 324:19 335:2,14 339:12 342:14 343:25 348:17 358:23 359:8 363:7 385:10 390:19 396:21 402:10 425:3 <b>background (1)</b> 354:23 <b>based (16)</b> 278:10 280:19 281:20 283:19 284:12 297:22 330:7 332:10 341:22 361:16,21 362:7 368:14 392:6 401:11 423:13 <b>basically (2)</b> 361:12 402:16 <b>basis (3)</b> 283:2 392:10 403:11 <b>Bates (4)</b> 302:2 323:24 430:10 430:15 <b>bearing (4)</b> 302:2 323:23 430:10 430:15 <b>bed (2)</b>	349:9,21 <b>beginning (4)</b> 305:15 353:20 379:23 404:2 <b>behavior (1)</b> 362:7 <b>behaviors (2)</b> 426:13,14 <b>belief (2)</b> 278:2 285:4 <b>believe (15)</b> 276:2 289:12 300:19 310:4 317:17 336:13 350:4 358:2 374:15 375:9 378:15 380:20 397:18 401:12 410:17 <b>believed (1)</b> 366:18 <b>believes (1)</b> 315:18 <b>beneath (5)</b> 288:7 291:4 296:17 304:16,25 <b>bent (1)</b> 347:17 <b>Berezofsky (3)</b> 270:14 271:8 272:2 <b>best (3)</b> 343:9 377:12 431:13 <b>better (4)</b> 304:17 340:14 343:24 417:11 <b>beyond (1)</b> 400:19 <b>big (2)</b> 303:11 306:17 <b>bit (5)</b> 299:21 344:19 349:7 423:19 424:3 <b>block (3)</b> 397:3,15,19 <b>blockage (9)</b> 290:18 292:16 293:14 397:17,22 399:5,9 408:21 411:8 <b>blocked (3)</b> 291:2 345:23 346:10 <b>blocking (1)</b> 400:15 <b>blood (9)</b> 344:4 345:24 346:6 346:14,25 347:24 349:6,22 431:15 <b>blood-glucose (2)</b>	348:24 349:6 <b>bodies (1)</b> 354:10 <b>body (4)</b> 349:12,13 371:25 405:25 <b>bothered (1)</b> 299:3 <b>bottle (1)</b> 317:11 <b>bottom (7)</b> 279:20 311:3 358:24 359:10 367:4,11 368:4 <b>boy (1)</b> 412:16 <b>brain (1)</b> 317:17 <b>break (8)</b> 332:14 334:14,18 335:9 344:6 385:3 400:21 402:2 <b>briefly (1)</b> 274:19 <b>bringing (1)</b> 383:17 <b>broader (1)</b> 400:8 <b>broke (1)</b> 402:14 <b>bubbles (2)</b> 358:21,22 <b>bulk (1)</b> 311:5 <hr/> <p style="text-align: center;"><b>C</b></p> <hr/> <b>call (1)</b> 294:23 <b>called (2)</b> 297:9 343:23 <b>calling (1)</b> 329:7 <b>calls (4)</b> 396:11,22,22,23 <b>camera (1)</b> 366:7 <b>cannula (4)</b> 347:16,18 371:20 405:25 <b>cap (1)</b> 292:16 <b>capacity (4)</b> 407:3,6,11,12 <b>Captioner (2)</b> 271:13 431:7 <b>care (6)</b>	359:2 360:11,13 361:13 395:11 429:10 <b>caregiver (1)</b> 311:23 <b>carried (1)</b> 275:23 <b>case (19)</b> 273:25 281:10,14 288:4,23 332:11 343:7 346:4 347:24 351:14 369:4 376:9 387:24 398:2 399:18 410:10 424:9 426:8 432:2 <b>cases (1)</b> 368:4 <b>catastrophic (4)</b> 286:12 287:13 288:21 288:21 <b>catch (1)</b> 349:14 <b>causal (1)</b> 344:6 <b>causally (4)</b> 308:21 339:10,21 340:12 <b>causation (2)</b> 291:10,10 <b>cause (7)</b> 312:12 353:20 380:24 399:15 400:21 407:5 425:23 <b>caused (7)</b> 290:8,12,20 291:22 292:15 397:22 418:18 <b>causing (1)</b> 345:24 <b>CCR (2)</b> 270:24 431:21 <b>CD (4)</b> 320:13 321:14,25 322:12 <b>CD-ROM (2)</b> 319:23 430:13 <b>CDE (2)</b> 425:15 427:10 <b>CDROM (4)</b> 319:20,21 320:4 430:12 <b>CDU (1)</b> 427:10 <b>Center (3)</b> 272:3,8,15 <b>certain (7)</b>	294:13 296:2,3 314:17 328:4 383:10 394:14 <b>certainly (8)</b> 285:20 304:17 309:16 354:2,6 390:5 394:3 424:17 <b>CERTIFICATE (1)</b> 431:2 <b>Certified (20)</b> 271:11,12,13,16 312:5,20,22 313:19 315:2,8,15 316:20 316:24 317:7,24 318:3 331:21 431:6 431:7,8 <b>certify (2)</b> 431:10,15 <b>cetera (1)</b> 348:17 <b>change (10)</b> 283:23 288:25 289:2 311:8 333:12,22,25 334:4 349:7,20 <b>changed (7)</b> 274:10 275:13 282:21 282:24 295:16 349:23 401:22 <b>changeover (1)</b> 333:18 <b>changes (1)</b> 329:6 <b>changing (2)</b> 333:2 344:5 <b>characterization (1)</b> 415:15 <b>check (7)</b> 301:2 344:4 347:23 348:23 349:5,11,22 <b>checking (2)</b> 301:18 358:21 <b>Cherry (1)</b> 272:4 <b>child (14)</b> 358:19,23,24 359:6,9 359:9,22 360:2,5,7 360:13 361:16 362:11 363:11 <b>child's (1)</b> 361:7 <b>choices (2)</b> 395:12,21 <b>choosing (1)</b> 354:23 <b>circuit (1)</b> 410:4
--	---	--	---	---

<b>circumstance (1)</b> 345:21	286:25 305:4	<b>conjunction (2)</b> 386:19 414:22	342:2,17,24 343:5	304:3 306:11,19
<b>circumstances (1)</b> 354:2	<b>communicating (1)</b> 288:5	<b>connect (5)</b> 314:7,9 332:6 382:16	348:17 399:20	310:17 312:15
<b>Civil (1)</b> 270:7	<b>communication (2)</b> 309:24 328:14	425:14	400:13 401:18	325:12 326:22
<b>clarification (6)</b> 292:21 305:24 327:8	<b>companies (2)</b> 377:20,22	<b>connected (4)</b> 278:13 330:16,25	<b>contaminants (3)</b> 299:6 400:9 401:5	327:3,22 328:8
352:5 413:20 415:3	<b>company (1)</b> 407:10	331:2	<b>contaminate (1)</b> 408:19	330:8 332:17,20,21
<b>clarified (1)</b> 274:16	<b>competently (1)</b> 403:24	<b>CONNECTICUT (1)</b> 270:2	<b>contaminating (2)</b> 279:20 291:16	334:4,9 335:13,20
<b>clarify (1)</b> 414:4	<b>complete (1)</b> 354:3	<b>connecting (11)</b> 292:13 297:15 303:15	<b>contamination (2)</b> 311:2 418:23	335:24 336:20,23
<b>clean (1)</b> 338:19	<b>completely (3)</b> 316:7 369:2 415:16	310:20 314:21	<b>contemplating (1)</b> 410:15	338:14 339:3
<b>clear (17)</b> 280:5,25 282:17	<b>complexity (1)</b> 423:24	354:9 371:24	<b>content (13)</b> 296:18 310:5,16	342:18 343:2 350:8
283:13 286:16	<b>complies (1)</b> 289:22	372:25 373:9 382:8	311:13,18 313:11	350:17,22 351:5
297:9 304:14,23,25	<b>compound (2)</b> 296:11 425:23	405:21	323:8,10,12,14	354:5 356:3,5
306:13 313:8	<b>comprised (1)</b> 386:21	<b>connection (10)</b> 313:16 344:6 373:6	326:11 337:2	357:10 359:10,23
352:11 354:3	<b>comprises (1)</b> 350:7	378:20 379:3 383:5	356:16	360:4 361:8,9
368:18 409:13	<b>computer (1)</b> 320:23	402:25 404:22	<b>context (1)</b> 305:14	363:15 365:24
410:14 411:19	<b>concede (1)</b> 356:19	406:7,17	<b>continue (2)</b> 273:6 358:16	367:5,14 368:21
<b>clearly (1)</b> 305:3	<b>concept (2)</b> 343:22 344:22	<b>connector (12)</b> 310:22 338:19 340:24	<b>continued (3)</b> 270:19 271:6 428:13	369:11 372:9
<b>Clinical (1)</b> 278:23	<b>concludes (3)</b> 334:22 402:6 429:12	375:13 379:4 396:3	<b>continuing (2)</b> 273:3 312:17	374:11,15 375:8,9
<b>closely (1)</b> 394:22	<b>conclusion (2)</b> 298:20 361:13	399:5,10 400:14	<b>control (1)</b> 374:6	375:15 378:3 388:2
<b>combination (2)</b> 304:13,22	<b>conduct (8)</b> 393:11 402:17 403:6	401:13 408:14,21	<b>convenient (2)</b> 417:23,24	389:3,23 390:6
<b>come (7)</b> 274:7 293:23 299:21	408:25 411:24	<b>connects (1)</b> 388:12	<b>convention (1)</b> 422:5	394:4 395:3 399:8
319:17 329:21	413:11 414:9 415:8	<b>consequence (3)</b> 346:14 348:14,14	<b>contrary (2)</b> 329:11 356:22	404:21,23 405:18
347:5 395:21	<b>conducted (9)</b> 402:22 403:3 405:16	<b>consequences (7)</b> 286:12 287:14 305:19	<b>control (1)</b> 374:6	408:6,8 409:10,21
<b>comes (1)</b> 315:17	405:19 406:3,15	309:18 348:2,11,12	<b>corrected (1)</b> 274:15	410:22 411:17
<b>comfortable (2)</b> 321:24 368:15	411:22 413:10	<b>consider (1)</b> 410:2	<b>correctly (9)</b> 291:14 314:12 344:18	415:13 417:2
<b>coming (2)</b> 273:24 390:23	415:5	<b>consideration (4)</b> 359:18 360:21 361:23	<b>cost (1)</b> 422:12	<b>counsel (1)</b> 289:23
<b>commanding (1)</b> 285:11	<b>conducting (1)</b> 422:3	362:5	<b>counter-clockwise (1)</b> 304:8	<b>counterclockwise (1)</b> 304:8
<b>commences (2)</b> 335:3 402:11	<b>conference (1)</b> 293:6	<b>consistent (3)</b> 333:3 426:18,19	<b>COUNTY (1)</b> 431:5	<b>COUNTY (1)</b> 431:5
<b>commerce (2)</b> 372:18 403:15	<b>confidence (1)</b> 424:5	<b>contact (1)</b> 384:24	<b>couple (5)</b> 308:4 335:7 354:20	<b>couple (5)</b> 308:4 335:7 354:20
<b>COMMISSION (1)</b> 432:25	<b>confused (3)</b> 405:4,6 412:8	<b>contacting (1)</b> 411:13	395:12 421:19	<b>course (1)</b> 328:22
<b>common (3)</b> 351:15 352:4,9	<b>confusing (1)</b> 296:11	<b>contain (1)</b> 328:7	<b>copy (9)</b> 300:20 302:14,16,22	<b>court (35)</b> 270:2 271:15,16
<b>Commonwealth (3)</b> 271:18 431:3,9	<b>confusion (1)</b> 339:25	<b>contained (3)</b> 300:2 337:2 378:17	302:24 306:24	282:3,12 289:11,18
<b>communicated (2)</b> 282:18 288:18		<b>containing (1)</b> 338:17	320:6 380:12,22	300:6,25 301:15,18
<b>communicates (2)</b>		<b>contains (1)</b> 338:22	<b>corporate (4)</b> 272:3 389:9 396:14	302:6 319:18,25
		<b>contaminant (18)</b> 292:12 293:15,18	407:12	323:18 324:4,5,20
		297:14 340:22	<b>corporation (1)</b> 396:8	325:4 339:14
		341:4,18,18,22,24	<b>correct (82)</b> 274:9,12 276:6	343:16 362:19
			277:23 283:4,15	373:17 385:13,17
			284:20 285:2 294:2	386:6 427:23,24
			294:19 295:5	428:4,8,11 429:4,6
			302:12 303:16	431:7,8

<b>cover (1)</b> 378:19	<b>damage (1)</b> 317:17	294:3,4 345:20 346:3	423:24	373:13 374:10,17
<b>covered (5)</b> 383:24 398:19 412:12 416:17 419:2	<b>damages (1)</b> 288:22	<b>defined (1)</b> 389:25	<b>depends (6)</b> 279:15 280:7 349:25 398:13 409:22,24	375:22 388:9 404:2 405:2,3,7,9
<b>covering (1)</b> 399:25	<b>danger (1)</b> 294:12	<b>degrees (1)</b> 348:19	<b>depict (2)</b> 284:24 320:20	<b>designed (3)</b> 375:2 405:2,5
<b>CPE (9)</b> 270:19,24 271:7 273:13 289:15 429:18 430:20 431:11,21	<b>dangerous (3)</b> 290:6,8 395:19	<b>deliber (1)</b> 362:4	<b>depicted (16)</b> 275:19,21 278:3 279:9 280:2,9 285:7 286:9,11 298:12 329:2,10 332:8 340:18 353:12 365:8	<b>designee (1)</b> 389:9
<b>CRC (2)</b> 270:24 431:21	<b>date (4)</b> 273:10 335:4 385:11 432:3	<b>deliberate (1)</b> 336:4	<b>depiction (2)</b> 275:23 285:5	<b>designs (1)</b> 378:2
<b>created (2)</b> 399:6 408:20	<b>dated (5)</b> 282:6,8 289:15 430:18,20	<b>deliberation (1)</b> 362:4	<b>depicts (4)</b> 285:8,19 326:21 358:19	<b>despite (1)</b> 413:8
<b>creation (1)</b> 394:21	<b>dates (1)</b> 338:15	<b>deliberia (1)</b> 362:4	<b>Deponent (2)</b> 432:4,21	<b>detach (1)</b> 314:8
<b>criticism (6)</b> 326:20 329:7,9 371:14 372:12 376:18	<b>Dave (10)</b> 281:7 291:23 300:10 300:12,12,14 325:23,25 334:15 334:17	<b>delivery (2)</b> 347:3 399:4	<b>deposed (2)</b> 407:2,10	<b>detached (1)</b> 280:24
<b>criticisms (19)</b> 275:2 327:18,23 328:13 370:19,21 370:24 372:6 375:24 376:3,4 377:9,13 378:5 382:4,18,25 397:24 398:21	<b>David (2)</b> 272:7 273:18	<b>Dennert (83)</b> 270:4 272:4 275:9,16 275:24 284:9 286:18 290:16,25 292:7 295:16 296:16 298:6,16,23 300:22 302:16 307:6 308:15,17,19 312:6,23 313:3,10 313:10,20 314:4 315:3,7,13 316:7 317:3,8,12,21,22,22 318:4,13,21 319:22 320:8 321:11,18,20 322:22 324:16 330:5,8,13,20,22,23 331:19,25 332:16 332:19 333:11,14 333:20 335:14,17 335:23 339:7,17 340:7 371:6 374:22 380:17 381:21 382:12 418:8 419:5 421:3,11,15 424:9 424:21,23 425:11 425:21 430:12	<b>deposition (35)</b> 270:19 271:6 273:3 273:24 274:2,5 278:11 283:3,8,25 287:24 289:13 298:14 300:17,18 300:21,23 301:6 305:16,16 325:14 329:25 331:8 342:23 368:6 372:8 379:25 392:15 398:6 410:6 426:5 429:12 431:11,12 432:3	<b>detaching (1)</b> 297:5
<b>criticize (1)</b> 382:22	<b>day (10)</b> 399:22 400:16 401:7 401:20 416:17 418:5 428:5 429:21 431:18 432:23	<b>dep (1)</b> 411:3	<b>depositions (1)</b> 416:17	<b>detail (2)</b> 313:5 334:8
<b>criticizing (1)</b> 377:10	<b>de (2)</b> 270:11 272:17	<b>Department (1)</b> 278:23	<b>deprived (1)</b> 291:12	<b>details (2)</b> 313:15 334:3
<b>critiques (1)</b> 325:7	<b>dealing (1)</b> 349:17	<b>dependent (1)</b>	<b>described (1)</b> 403:19	<b>determine (6)</b> 353:4 354:8 369:2 391:20 404:10 407:24
<b>CRR (2)</b> 270:24 431:21	<b>Debra (4)</b> 270:24 271:10 431:6 431:21		<b>describes (2)</b> 284:3,4	<b>determined (2)</b> 293:11 360:12
<b>Cuker (3)</b> 270:14 271:8 272:2	<b>decided (2)</b> 355:3 372:24		<b>describing (2)</b> 281:9,12	<b>determining (5)</b> 404:2,3,4,6,7
<b>current (1)</b> 284:18	<b>decision (3)</b> 291:5 336:4 359:18		<b>description (7)</b> 276:4 278:11 304:13 315:18 320:9 430:8 430:17	<b>developed (5)</b> 280:13 372:17 390:18 390:21,22
<b>customs (1)</b> 393:10	<b>decrease (1)</b> 424:19		<b>design (13)</b> 274:22 351:23 369:9	<b>developer (1)</b> 353:2
<b>cut (3)</b> 393:2 423:19 425:7	<b>dedicated (1)</b> 353:3			<b>development (2)</b> 277:19 353:8
<b>cuts (1)</b> 374:5	<b>default (1)</b> 317:5			<b>deviation (1)</b> 355:14
<b>CV (2)</b> 270:11 272:17	<b>defective (2)</b> 290:7 395:19			<b>device (3)</b> 393:23 402:21 423:15
	<b>Defendant (2)</b> 272:10,17			<b>devices (9)</b> 270:10 272:17 279:8 280:2 282:20 284:23 417:21,22 425:20
	<b>Defendants (1)</b> 270:12			<b>Diabeetic (1)</b> 312:20
<b>D</b>	<b>deficiencies (1)</b> 296:7			<b>Diabetes (18)</b> 270:8,10 272:11,11 312:5,22 313:19 314:3 315:2,8,15 316:20,25 317:8,13 317:24 318:3 331:21
<b>D (1)</b> 430:2	<b>deficient (2)</b> 275:6 328:16			<b>Diabetic (1)</b> 312:20
<b>d/b/a (2)</b> 270:8 272:10	<b>define (4)</b>			

<b>die (1)</b> 287:21	276:8,18 381:2	307:24 308:2	<b>educators (2)</b> 299:4 311:24	432:1
<b>difference (2)</b> 294:8 407:9	<b>discrepancy (2)</b> 306:21 307:2	<b>doubtful (1)</b> 316:7	<b>effect (1)</b> 381:7	<b>error (1)</b> 396:18
<b>different (24)</b> 275:8,18 283:11 293:22,23 300:17 337:16 347:4 348:7 348:19 349:18,18 355:15 362:5,6 377:21 394:18 400:11 401:15 422:6 424:22 425:10,24 426:14	<b>discussed (5)</b> 298:14 306:8 313:4 424:22 425:10	<b>dozen (1)</b> 420:12	<b>effective (5)</b> 319:3,8 345:15 404:13 422:12	<b>errors (2)</b> 404:6,8
<b>differently (2)</b> 298:23,24	<b>discussion (1)</b> 313:14	<b>Dr (8)</b> 292:14 293:11 333:17 341:23 343:6 400:18 410:12 420:23	<b>efficient (1)</b> 368:15	<b>Esq (2)</b> 282:10 430:19
<b>difficulties (6)</b> 277:2 384:14 393:4 394:9 412:10 424:25	<b>disk (1)</b> 323:15	<b>drafted (1)</b> 336:12	<b>either (17)</b> 286:13,21,23 287:9 287:15 288:2 298:25 307:23 315:5 334:8 336:10 340:22 343:15 346:25 398:5 401:7 401:19	<b>ESQUIRE (3)</b> 272:2,7,14
<b>diluent (1)</b> 316:4	<b>displays (1)</b> 326:25	<b>drive (1)</b> 272:3	<b>elaborate (1)</b> 280:10	<b>essentially (3)</b> 336:25 337:6 340:18
<b>Diplomat (2)</b> 271:11 431:6	<b>disregarded (1)</b> 367:19	<b>dropping (1)</b> 405:22	<b>eleven (2)</b> 295:18 333:17	<b>et (1)</b> 348:17
<b>direct (7)</b> 298:5 308:14 309:13 317:11,14 418:22 420:25	<b>dist (1)</b> 407:9	<b>dry (2)</b> 338:20 344:8	<b>employee (1)</b> 407:10	<b>evaluate (2)</b> 378:8,25
<b>directed (2)</b> 345:5 372:8	<b>distinguish (3)</b> 293:25 327:6,13	<b>due (3)</b> 290:17 293:13 346:15	<b>employees (1)</b> 278:22	<b>evaluated (2)</b> 376:8 378:10
<b>directing (2)</b> 282:14 285:12	<b>District (6)</b> 270:2,2 271:14,15 431:7,8	<b>duly (1)</b> 431:12	<b>encountered (1)</b> 354:2	<b>evaluation (3)</b> 352:16 409:5,6
<b>direction (1)</b> 431:14	<b>Division (2)</b> 270:8 272:11	<b>dumped (2)</b> 349:11,13	<b>ends (1)</b> 306:25	<b>evening (4)</b> 335:19 401:8 418:9 419:6
<b>directions (1)</b> 331:10	<b>doc (1)</b> 289:9	<b>duty (7)</b> 387:12 403:6 411:24 413:11 414:9 415:8 415:10	<b>engagement (1)</b> 351:13	<b>event (1)</b> 291:10
<b>directs (1)</b> 379:9	<b>doctor (3)</b> 282:14 299:2,3	<b>DVD (5)</b> 334:22 335:3 402:6 402:11 429:12	<b>engineer (1)</b> 353:7	<b>eventually (2)</b> 275:8 370:3
<b>discipline (1)</b> 343:23	<b>doctors (2)</b> 309:21 337:3	<b>Dwayne (1)</b> 300:25	<b>engineering (1)</b> 393:24	<b>Everybody (1)</b> 427:19
<b>disconnect (3)</b> 339:8,19 427:22	<b>document (14)</b> 281:11 301:25 306:18 310:2 323:22 324:23 325:8 370:15 379:18 391:16 393:20 430:9,14,22	<b>E</b>	<b>ensure (9)</b> 292:11 297:11 347:12 359:2 387:16,19 388:18,23 414:21	<b>evidence (40)</b> 295:15,22 296:5,14 296:15,19 298:2,5 298:11,19 307:5,8 307:13,19 308:15 312:21 314:2 315:6 317:11 330:4,12 331:18,25 332:10 332:11 341:6,17 342:23 343:7 395:24 399:18 400:12 401:4,16 418:4,7,15 419:3,14 421:2
<b>disconnected (8)</b> 361:19 393:8 394:11 412:22 418:10 419:7,19 421:5	<b>doing (27)</b> 279:2 288:8 291:6 294:12,12,21,23 296:23,25 297:21 314:11,19 332:8 333:4,25 351:8 368:12,13,20 382:19 391:3 406:24 416:3 418:21 420:17 423:5 426:20	<b>E (2)</b> 430:2,7	<b>ensured (7)</b> 310:23 311:23 386:24 388:5 390:14 391:9 406:21	<b>exact (3)</b> 302:16 326:11 350:23
<b>disconnecting (4)</b> 363:21 366:8 367:20 396:4	<b>documented (1)</b> 368:11	<b>earlier (6)</b> 312:3 362:22 363:10 376:12 399:20 426:5	<b>ensuring (1)</b> 295:3	<b>exactly (22)</b> 286:9,10,14,15,20,22 287:12,13 295:22 297:21 299:16 305:18,20 316:22 317:16 326:3 332:19 345:11 368:20 383:22 384:2 388:4
<b>disconnection (3)</b> 364:5,23 410:21	<b>documents (2)</b> 281:13 284:20	<b>easiest (2)</b> 293:19 395:21	<b>entire (2)</b> 353:3 373:5	<b>EXAMINATION (4)</b> 273:15 358:9 421:22 423:9
<b>discover (1)</b> 410:16	<b>dosage (1)</b> 389:19	<b>East (1)</b> 272:3	<b>entirely (1)</b> 378:2	
<b>discovered (1)</b> 297:3	<b>doubt (2)</b>	<b>Eastern (2)</b> 271:15 431:8	<b>entitled (8)</b> 301:25 319:22 323:22 324:24 430:10,12 430:14,22	
<b>discovery (3)</b>		<b>education (6)</b> 309:8,8,15 314:14 316:25 321:16	<b>ergonomics (1)</b> 352:22	
		<b>Educator (15)</b> 312:5,20,22 313:20 314:3 315:2,9,15 316:21,25 317:8,13 317:24 318:3 331:21	<b>ERRATA (1)</b>	

<b>examined (1)</b> 273:14	<b>explain (7)</b> 285:17 287:23 290:12 291:19 298:16 377:5 386:16	361:6	320:16 323:19,23 324:12 350:22 363:14 373:8 382:6 396:6,19 399:13 430:14	278:25 279:17 286:6 297:7 329:14
<b>example (7)</b> 295:3 322:21 344:2,4 347:14 349:5 423:2	<b>explaining (1)</b> 376:11	<b>Falls (1)</b> 272:3		<b>follow (12)</b> 286:14,14,22 288:19 331:22 332:2,19,23 336:4 347:6 358:8 399:12
<b>Exclude (1)</b> 401:9	<b>explicit (1)</b> 345:16	<b>familiar (1)</b> 423:25	<b>fills (1)</b> 358:19	
<b>excuse (9)</b> 273:9 284:2 311:3 335:10 350:6 387:8 397:10 417:7 427:4	<b>explored (1)</b> 412:13	<b>family (1)</b> 374:24	<b>finally (1)</b> 314:13	<b>follow-up (2)</b> 386:16 421:19
<b>exemplar (3)</b> 302:17 371:3 380:17	<b>exploring (1)</b> 402:18	<b>famished (1)</b> 400:22	<b>find (4)</b> 354:18 368:8,9 409:2	<b>followed (10)</b> 288:16,17 295:4 317:23 330:23 331:10 339:7,18 340:8 369:2
<b>exhaustively (1)</b> 400:3	<b>exposed (1)</b> 350:24	<b>Fargo (1)</b> 272:8	<b>finding (2)</b> 402:15 408:11	
<b>exhibit (36)</b> 282:4,8,16 289:13,14 289:21 300:7,16,21 301:7,24 302:10 319:19,21 320:3 321:7,19 322:15 323:18,21 324:6,8 324:22,23 325:10 326:4,20 350:4 379:20 380:2 430:9 430:12,14,18,20,22	<b>express (1)</b> 377:12	<b>fashion (5)</b> 352:23 415:23 416:2 418:21,22	<b>findings (1)</b> 398:23	<b>following (5)</b> 294:15,15 339:13 385:16 386:5
	<b>expressed (1)</b> 372:7	<b>FDA (17)</b> 369:16 391:13 392:5 392:25 393:9,13,14 393:17,21,22 394:3 394:4 407:18 409:10,20 410:2,9	<b>fine (8)</b> 285:23,25 383:6 387:19 389:14,16 417:9 422:9	<b>follows (2)</b> 273:14 307:12
	<b>eyewitness (1)</b> 419:12		<b>finish (2)</b> 274:19 292:23	<b>forced (1)</b> 394:17
	<b>eyewitnesses (1)</b> 421:14	<b>feasibility (1)</b> 403:7	<b>finished (2)</b> 369:24 386:2	<b>forget (4)</b> 308:5 319:13 426:11 426:12
	<b>F</b>	<b>Federal (1)</b> 394:2	<b>fir (1)</b> 345:25	<b>forgot (3)</b> 335:17,23 336:2
	<b>fact (18)</b> 278:9 288:23,24 298:11 307:25 312:15 315:23 329:5 330:9 340:7 342:16 346:9 360:22 361:16 407:14 415:4 418:16,21	<b>felt (1)</b> 274:15	<b>firm (1)</b> 273:18	<b>form (17)</b> 296:10 298:9 299:10 308:24 318:19 322:7 353:19 397:9 398:4 407:5,20 409:12,17 410:24 412:2 420:9 423:18
<b>exhibits (3)</b> 283:25 284:13 430:16	<b>factors (33)</b> 274:21 275:3 282:25 352:21 391:4,19,21 392:22 393:12,24 402:18,21 403:7,20 403:24 405:17 406:4,11,16,20 407:16,23,25 408:13,23 409:4,6 410:18 411:21 413:9,12 414:10 415:6	<b>field (3)</b> 318:24 353:7,12	<b>first (18)</b> 274:2 279:15 282:19 289:10 293:24 310:14 316:2 325:9 326:20 333:11 336:16 346:2 356:9 365:14,24 389:6 410:6 416:17	<b>forth (4)</b> 279:6 398:14 424:5 431:12
<b>exist (2)</b> 276:20 350:12		<b>figuratly (1)</b> 288:17		<b>forward (1)</b> 275:23
<b>expect (9)</b> 297:21 309:18 310:3 317:18 342:9 362:5 368:14 417:19 424:20		<b>figure (4)</b> 287:5 315:24,25 364:6		<b>found (2)</b> 401:21 418:9
<b>expected (5)</b> 408:23,24 409:2,3 410:16		<b>file (2)</b> 274:6 320:23	<b>five (3)</b> 385:5 400:23 422:8	<b>four (2)</b> 349:15 368:22
<b>expedited (1)</b> 428:2		<b>fill (30)</b> 292:15 297:2,18 314:8 333:16 336:8 339:8,19 346:9 348:12 349:9 371:21 372:4 376:15 377:16 378:12 388:3 389:3 389:7 390:10,16 397:7,14,20,21 418:17,25 419:5 420:13 425:13	<b>flip (5)</b> 328:22,24 363:20 366:7,17	<b>fourth (1)</b> 289:25
<b>expending (1)</b> 422:10			<b>flipped (4)</b> 297:12 329:3,5 366:16	<b>frame (5)</b> 370:5 375:16 390:3 390:19 400:20
<b>experience (4)</b> 345:3 353:25 362:8 426:15			<b>flipping (3)</b> 288:20 328:25 366:24	<b>frankly (1)</b> 326:10
<b>experienced (5)</b> 290:16,25 316:6 418:16 424:18	<b>facts (1)</b> 298:19		<b>flow (1)</b> 293:12	<b>front (1)</b> 379:18
<b>expert (5)</b> 409:9,10,20 410:2,9	<b>failed (3)</b> 292:6,10 376:25		<b>fluid (2)</b> 279:18 291:15	<b>frozen (3)</b> 362:16,19,20
<b>expertise (2)</b> 318:24 344:16	<b>failure (8)</b> 290:3,4 291:11 308:20 332:10 345:4,6 402:17	<b>filled (6)</b> 295:20 330:25 332:7 335:18 418:8 419:16	<b>focus (1)</b> 376:17	<b>full (2)</b> 289:25 364:12
<b>experts (1)</b> 351:16	<b>fair (6)</b> 275:10 284:16 287:6 295:10 322:13	<b>filling (17)</b> 275:12 297:23 303:14 303:18 307:21	<b>focussed (1)</b> 291:9	<b>fully (1)</b>
<b>EXPIRES (1)</b> 432:25			<b>focussing (1)</b> 378:4	
			<b>folks (5)</b>	

412:12 <b>further (4)</b> 358:6 427:13,16 431:15 <b>fuzzy (1)</b> 332:4	274:18 277:8 281:19 297:10 298:9 302:19 306:3 308:11 318:19 324:18 328:3 349:9 355:4 362:23,24 373:22 376:10 407:20 408:11 411:4 412:4 413:16 415:19 416:21 422:14 427:6	<b>groups (1)</b> 353:8 <b>guarantee (2)</b> 367:12 421:25 <b>guard (48)</b> 278:5,14,17 288:7 297:24 304:7,9,24 327:2,15,21 333:8 339:9,20 340:16 341:13 342:7,8 356:21 358:25 359:11,23 360:3,15 361:15,18 363:22 364:4,22,25 365:13 365:17,24 366:9,11 366:20 367:5,21 368:25 369:6 396:4 410:21 418:10,14 419:9,18 421:6,8	<b>hands-on (1)</b> 319:2 <b>Hang (1)</b> 336:18 <b>happen (6)</b> 291:22 312:15 325:17 328:4 349:14 354:6 <b>happened (4)</b> 295:23 312:10 362:21 362:22 <b>happening (1)</b> 420:18 <b>happens (1)</b> 420:21 <b>happy (2)</b> 302:19 370:13 <b>hard (2)</b> 327:6,13 <b>Haverty (6)</b> 274:8 282:9 325:15 325:18 326:8 430:19 <b>hazard (38)</b> 294:24,25 297:13 298:25 299:5 300:4 310:25 311:25 314:18 315:13 316:13 317:2,3,4,5 317:9 328:10 345:17,21,22,23 346:4,8,12 377:16 378:13 379:6 384:8 386:12 388:16 391:8 395:5,7 399:6 408:20 410:14,19 411:7	340:17 341:12 342:8 359:3 363:5 365:17 368:23 385:8 402:8 <b>hello (1)</b> 412:17 <b>help (1)</b> 323:19 <b>hereinbefore (1)</b> 431:11 <b>hereunto (1)</b> 431:17 <b>Hey (1)</b> 395:6 <b>Hi (1)</b> 358:11 <b>high (2)</b> 346:14,25 <b>highlighted (1)</b> 329:2 <b>highly (3)</b> 307:24 316:6,24 <b>Hill (1)</b> 272:4 <b>HINE (1)</b> 272:14 <b>hiring (1)</b> 416:5 <b>hold (6)</b> 300:14 304:7 366:3,3 369:5 393:19 <b>holding (4)</b> 284:25 297:3 365:20 410:8 <b>hours (1)</b> 349:23 <b>human (33)</b> 274:21 275:3 282:25 352:21 391:3,19,21 392:22 393:11,24 402:18,21 403:6,20 403:24 405:16 406:3,10,15,20 407:16,23,25 408:13,23 409:4,5 410:18 411:20 413:9,12 414:10 415:6 <b>hundred (1)</b> 345:14 <b>hundreds (1)</b> 396:23 <b>hypothetical (6)</b> 280:12,17 281:18,25 348:3 349:19
<hr/> <b>G</b> <hr/> <b>gather (3)</b> 351:18,20 400:2 <b>gears (1)</b> 299:20 <b>gen (1)</b> 343:24 <b>general (3)</b> 343:24 344:23 348:23 <b>generally (2)</b> 345:5 352:12 <b>Georgia (1)</b> 272:16 <b>GERARD (1)</b> 272:21 <b>getting (11)</b> 279:19 287:25 291:15 292:8 297:14 299:6 341:19 347:25 389:18 394:11 422:11 <b>Gharabli (8)</b> 389:11 391:18 392:7 392:10 394:20 396:7 407:2,21 <b>Gharabli's (1)</b> 408:5 <b>give (8)</b> 280:11,16 336:16 347:14 369:19 370:13 373:24 391:15 <b>given (16)</b> 276:4 281:21 309:17 310:18,25 311:7 316:20 317:23 319:5 330:24 331:20 343:7 362:11 417:5 424:7 431:13 <b>gives (1)</b> 294:11 <b>giving (3)</b> 285:23,24 310:23 <b>global (1)</b> 295:6 <b>glucose (1)</b> 344:4 <b>go (26)</b>	<b>God (2)</b> 393:2 425:8 <b>going (50)</b> 276:13 277:10 297:19 308:5,9 312:12 316:3,13,16,17 317:19 320:4 331:3 334:21 344:9,11,13 346:20 349:21 367:6 371:10 372:24 378:6,22 379:13 380:24 383:9 384:6 386:9 387:2,5 390:25 395:11,13,16 398:3 400:20,23 402:5 404:11 406:22 407:4 412:14 414:2 415:21,25 421:17 423:17,23 424:2 <b>good (10)</b> 273:7,17 286:23 349:4 351:18 417:12 426:9 427:5 427:20,20 <b>Google (1)</b> 351:16 <b>gotten (1)</b> 303:7 <b>grab (2)</b> 336:19 389:9 <b>grabbed (2)</b> 359:14 360:17 <b>graphic (1)</b> 285:9 <b>great (1)</b> 429:3 <b>greater (1)</b> 334:8 <b>green (1)</b> 316:3 <b>ground (3)</b> 286:25 400:2 412:15 <b>group (1)</b> 353:3	<b>guess (3)</b> 292:20 326:14 356:4 <b>guidance (3)</b> 393:22 394:4,6 <b>guide (25)</b> 300:2,8 302:2,11,22 303:5,6,14 306:16 306:23 307:7,10 308:21 309:3,6,25 310:17 311:6,10 351:3,7 379:10 381:9,23 430:10 <b>guideline (2)</b> 393:16,18 <b>guides (1)</b> 356:15 <b>guys (8)</b> 315:24 334:12 372:23 372:24 385:2 390:22 391:2 395:6	<hr/> <b>H</b> <hr/> <b>H (1)</b> 430:7 <b>half (2)</b> 388:14 395:15 <b>hand (15)</b> 282:4 285:10,13,20 285:20 286:5 287:5 288:10 300:7 324:21 416:8,8,12 416:24 431:18 <b>handed (3)</b> 320:2 324:6 359:7 <b>hands (5)</b> 284:24 285:6 288:25 358:20,22	<b>hazard's (1)</b> 388:15 <b>hazards (3)</b> 294:20,22 404:8 <b>heading (1)</b> 380:25 <b>healthcare (3)</b> 337:3,14,23 <b>hear (16)</b> 273:20 292:4 293:2 321:2 343:10 353:20 357:12 358:11 371:8 372:14 373:20 409:15 412:18,20 419:25 425:2 <b>heard (1)</b> 423:20 <b>held (12)</b> 271:7 277:12 334:24

<b>I</b>	423:15,16 424:11 424:13 427:6	425:14	349:8,20 354:10,19 355:6,17,17 360:14 369:15,24 370:7,9 370:17,20,23 371:4 371:15,18,23 372:13,21 373:10 375:11,14,25 376:5 376:13,19 378:5,7 378:10,16,21 379:2 379:5,8,10 380:9,12 380:17 381:8,9,20 381:22,24 382:8,12 382:13,16 383:3,11 383:13,17 388:12 390:25 391:20,23 392:5 393:13 394:23,25 395:2,4 395:14 399:7,22 400:14 401:6,19,20 402:24 403:17 404:20 405:8,12,20 406:5,8,17 407:24 408:3,14 411:23 413:14 414:13 418:6 421:3,4 425:14 427:3	<b>instructing (3)</b> 364:2,19 382:15 <b>instruction (12)</b> 280:4 288:11 294:10 305:17 306:9 318:4 318:7,15 329:14 330:23 376:20,25 <b>instructional (5)</b> 319:20,23 320:3,4 430:13 <b>instructions (76)</b> 285:24 286:4 287:9 289:4 290:4 291:12 293:25 294:3,4,6,16 294:17 295:4,8,12 295:13 296:22 297:6 299:25 308:10 311:13,21 316:9,15,20 317:5 317:23 319:4,7,11 319:16 331:12,14 331:20 336:5 339:7 339:18 340:8 351:4 353:17 354:4 356:22,24 357:9 367:20 371:18,23 377:14 378:11,20 384:3,5 386:8,25 387:8,12,17,20,22 388:7,19 390:15 391:10 399:13 404:12 417:4,5,8,10 417:12,14,17,18 418:19 426:7,16 <b>instructors (1)</b> 309:9 <b>instructs (2)</b> 285:5 353:15 <b>insulin (128)</b> 275:20 277:22,22 278:12,18 279:10 279:19 284:25 287:20 290:17,20 291:15 292:8 293:12,14,16 297:4 297:24 298:21 302:2,15 304:15 312:24 314:20 315:4 317:10 320:17 326:22 328:15 333:3,4,5,6 333:9,21,24 334:3 340:9,17,24 341:3,7 341:10,12,14,15,22 341:25 342:6,8,20 343:4,6,8,18,21
<b>IBM (1)</b> 353:2 <b>identical (1)</b> 326:13 <b>identification (6)</b> 282:11 289:17 302:4 319:24 323:25 325:2 <b>identified (7)</b> 288:14 350:7 391:7 395:7 396:23 408:17 409:7 <b>identify (6)</b> 294:24,25 311:25 316:18 348:22 381:4 <b>IFU (144)</b> 275:6,8,14,18,19,23 276:5,7,15 278:2,9 279:7,25 280:13,17 281:9 282:20,25 283:9,23 284:8,14 284:18,22 285:8,11 285:19 286:7,14,15 286:23,25 288:5,14 291:7,21 292:5 295:7,11,13,14 296:7,19 297:6 304:18 305:15 308:8 310:3,19 311:18 318:10 324:19,22 325:10 325:11 327:20 329:5,8 330:5,10 331:15,19,22 332:2 332:9,11,16,19,23 335:11,18,24 336:5 336:9 339:2 351:7 351:10 365:25 369:2 370:7,20,22 370:23 371:15,17 371:17,23 372:8,13 373:2 375:25 376:4 376:12,13,16,22 377:7,8,9,10 378:5 378:7,9,15,16,25 379:9 380:9,13,16 380:22 381:7,21 382:6,12,15,23,24 383:3,4,12,17,23,23 384:6,8 386:10,11 387:3 388:21 394:14,15,18,23 395:10 404:12 411:10,15,17	423:15,16 424:11 424:13 427:6 <b>IFU's (1)</b> 328:14 <b>IFUs (11)</b> 275:11 276:14 278:10 284:4 292:6 296:21 311:4 356:15 368:21 370:16 424:18 <b>ignored (1)</b> 406:11 <b>II (1)</b> 270:1 <b>Ileana (3)</b> 272:14 276:25 373:20 <b>importance (2)</b> 299:4 310:19 <b>important (2)</b> 328:22 426:17 <b>importantly (1)</b> 279:16 <b>impression (1)</b> 364:18 <b>improper (4)</b> 290:5 294:21 299:24 347:3 <b>improperly (2)</b> 270:9 272:11 <b>in-depth (1)</b> 410:6 <b>in-person (2)</b> 313:21 314:5 <b>inadequacy (1)</b> 291:20 <b>inadequate (4)</b> 295:14 316:21 317:6 353:16 <b>inappropriate (1)</b> 353:16 <b>incident (14)</b> 308:22 315:19 317:18 335:12 341:20 343:2 371:7 380:18 390:5 399:23 400:16 401:8,9,9 <b>inclination (1)</b> 278:25 <b>include (4)</b> 354:22 404:11 417:10 417:16 <b>included (6)</b> 283:25 284:8 339:2,6 339:17 402:25 <b>including (4)</b> 279:18 291:15 404:22	425:14 <b>incomplete (1)</b> 281:25 <b>inconsistent (1)</b> 336:9 <b>incorporating (1)</b> 393:23 <b>incorporation (1)</b> 405:8 <b>incorrectly (2)</b> 314:19 342:6 <b>independent (5)</b> 377:19 388:22 413:11 414:9,11 <b>independently (2)</b> 414:22 415:8 <b>indicate (1)</b> 353:15 <b>indicating (3)</b> 359:15 365:20,21 <b>indirect (1)</b> 298:10 <b>individual (3)</b> 407:3,6,11 <b>industry (3)</b> 393:2,10,22 <b>ineffective (1)</b> 317:6 <b>inform (3)</b> 294:18 317:3,4 <b>information (41)</b> 278:24 281:21,22 291:13 294:11 308:7 311:24 318:12 322:14 337:11,12,17,22,25 338:18,23 345:16 351:19,20 353:5 355:3,23 356:8,10 362:11 363:14 372:25 375:7 378:15 404:9 407:16 419:23 420:4,5 422:11 424:23 425:11,19 426:4,19,22 <b>informed (2)</b> 292:11 317:8 <b>infusion (107)</b> 283:10 284:9 290:7 291:13,21 295:17 296:23 303:16 304:18 310:21 311:5,7 313:16 330:10 332:6 333:21 347:21	349:8,20 354:10,19 355:6,17,17 360:14 369:15,24 370:7,9 370:17,20,23 371:4 371:15,18,23 372:13,21 373:10 375:11,14,25 376:5 376:13,19 378:5,7 378:10,16,21 379:2 379:5,8,10 380:9,12 380:17 381:8,9,20 381:22,24 382:8,12 382:13,16 383:3,11 383:13,17 388:12 390:25 391:20,23 392:5 393:13 394:23,25 395:2,4 395:14 399:7,22 400:14 401:6,19,20 402:24 403:17 404:20 405:8,12,20 406:5,8,17 407:24 408:3,14 411:23 413:14 414:13 418:6 421:3,4 425:14 427:3 <b>initial (2)</b> 311:8 426:17 <b>injection (2)</b> 290:17,19 <b>injured (1)</b> 333:14 <b>injuries (1)</b> 290:20 <b>injury (10)</b> 279:22 290:9,13 291:9 339:10,22 340:12 344:8 345:7 421:16 <b>innate (1)</b> 424:4 <b>insert (1)</b> 405:24 <b>insertion (1)</b> 379:4 <b>inside (6)</b> 361:7 399:21 400:13 401:6,13,18 <b>install (2)</b> 379:10 381:9 <b>instruct (2)</b> 281:2 292:10 <b>instructed (6)</b> 315:8 317:12 332:20 332:24 335:24 388:24	

345:24 346:7,11,15 347:3,9,16,18,20,25 348:4,17 349:11,13 355:6 357:21 358:23 359:3,7,8,9 359:13,22 360:2,7 360:14 361:14,17 363:21 364:21 365:11,17,23 366:8 366:11,15,19 367:3 367:10 368:24 369:5 374:18,20,23 375:21 382:7,7 387:25 396:2,5 399:4,11 400:13 401:10,13,18,23 408:19,19 410:19 411:7,12 418:11,12 419:7,17,19 420:15 421:6,6 425:12 430:10 <b>integrated (1)</b> 373:10 <b>intend (2)</b> 288:15,16 <b>intended (2)</b> 288:15 367:16 <b>intent (2)</b> 286:16 378:18 <b>intention (2)</b> 288:13 367:9 <b>interested (1)</b> 431:16 <b>Internet (2)</b> 350:13 352:12 <b>interpose (1)</b> 397:10 <b>interpret (1)</b> 300:15 <b>interpretation (2)</b> 287:6,7 <b>interpreting (1)</b> 365:6 <b>interrupt (1)</b> 306:5 <b>introduced (1)</b> 372:17 <b>introducing (1)</b> 403:14 <b>inverted (2)</b> 328:24 341:14 <b>investigation (1)</b> 352:16 <b>involved (6)</b> 333:15 394:21 395:5 407:22 413:13	422:6 <b>involving (2)</b> 391:22 408:2 <b>issue (13)</b> 282:19 314:14 333:13 372:3 373:7 376:15 387:23 389:3,18 397:25 420:18 422:16,24 <b>issued (4)</b> 357:7 390:15 394:16 398:14 <b>issues (4)</b> 319:10 349:18 351:17 398:2 <b>items (1)</b> 419:20 <hr/> <b>J</b> <hr/> <b>J (9)</b> 270:19 271:7 273:5 273:12 289:15 429:18 430:4,20 431:11 <b>Jersey (5)</b> 271:17,18 272:4 431:8,9 <b>job (2)</b> 270:25 304:17 <b>join (2)</b> 289:7 397:12 <b>Jr (9)</b> 270:19 271:7 273:5 273:12 289:15 429:18 430:4,20 431:11 <b>June (11)</b> 282:6,9 337:14,17,20 337:20 356:2,17 389:22 397:4 430:18 <b>Jurat (1)</b> 428:14 <b>jury (1)</b> 383:9 <hr/> <b>K</b> <hr/> <b>keep (6)</b> 344:8 360:7,13 366:23 394:10 412:14 <b>keeping (2)</b> 338:18 361:14 <b>kept (3)</b> 359:9,22 360:2 <b>Kevin (2)</b>	282:9 430:19 <b>Kilowitz (1)</b> 333:17 <b>kind (9)</b> 287:16 293:9 332:3 344:6 354:13,15 404:6,7,9 <b>kinked (1)</b> 347:21 <b>Klimowicz (10)</b> 292:14,14 293:11 342:16,22 343:6 400:18 401:11 410:12 420:23 <b>Klimowicz's (4)</b> 290:15 315:18 341:23 342:13 <b>knew (6)</b> 298:23,24 318:13 367:18 375:15 390:11 <b>know (135)</b> 276:22 279:5,17 280:18 281:10 283:7,9 286:2,9 287:22 288:3,19 292:25 293:15 295:23 297:11 302:13,15 306:18 306:23 309:11 313:19 314:3,6,9,11 314:12 315:10,21 316:5,22,23 318:13 320:12 321:19,24 322:3,5,7,7,10,10 322:22 323:5,10,15 324:11,14,15 326:15 329:15,18 333:9 341:17,21,24 341:25 343:3,18 345:17 347:2 348:9 348:23 349:9 350:15,16,18,19,23 350:25 351:8,21 354:19,22 355:9,18 355:21 356:9,11,14 356:18 357:5,5 360:25 361:3 362:9 362:10 363:16 367:8 368:8 369:25 370:4,12,22 371:13 372:23 373:5 374:19 375:16,19 377:4 378:3 379:14 379:15,18 380:3,4 381:17 383:8,14,15	391:11,17 392:14 394:3 398:12,18 400:6,11 401:8 407:5,9,14 409:13 410:24 412:13 415:12 416:7,9,9 418:18 420:21 421:10 426:19 428:4 <b>knowing (1)</b> 361:8 <b>knowledge (2)</b> 312:15 335:17 <b>knows (1)</b> 297:11 <hr/> <b>L</b> <hr/> <b>lab (1)</b> 315:23 <b>labeled (2)</b> 303:20 319:19 <b>lack (2)</b> 343:23 375:21 <b>laid (1)</b> 328:17 <b>Lake (1)</b> 272:3 <b>language (8)</b> 304:22 336:13,23 337:9 381:6 383:11 383:12 412:6 <b>large (1)</b> 355:12 <b>larger (1)</b> 296:24 <b>lawsuit (1)</b> 333:13 <b>lead (2)</b> 279:21 298:19 <b>leading (1)</b> 418:24 <b>learned (3)</b> 319:14 389:6,17 <b>leaves (1)</b> 287:4 <b>leaving (1)</b> 410:10 <b>leeway (1)</b> 286:22 <b>left (3)</b> 278:12 416:13,25 <b>left-handed (1)</b> 285:21 <b>LEGAL (1)</b> 272:21 <b>length (1)</b>	311:5 <b>Lenox (1)</b> 272:16 <b>let's (14)</b> 289:8,8,9 299:20 321:5 324:18 336:11 350:3 367:15 385:4,4,5 394:11 413:16 <b>letter (11)</b> 282:8 337:13,17 338:6,10,11,21 356:2,12 397:4 430:18 <b>letters (2)</b> 389:22 420:20 <b>level (3)</b> 348:24 349:6 396:14 <b>likelihood (1)</b> 311:6 <b>limit (1)</b> 413:23 <b>limitation (1)</b> 426:11 <b>liquid (7)</b> 306:8 328:4 341:3 399:19 400:12 401:5,17 <b>liquids (1)</b> 400:9 <b>listed (3)</b> 380:9,25 398:17 <b>listen (1)</b> 293:2 <b>literally (1)</b> 288:16 <b>litigation (3)</b> 351:13 352:13,19 <b>little (10)</b> 299:20 310:10,11 340:14,15 344:19 349:7 385:3 423:19 424:3 <b>LiveNote (1)</b> 271:13 <b>long (4)</b> 306:23 308:3 310:2 429:9 <b>look (8)</b> 282:2 308:10 320:5 327:7 331:4 361:17 370:14 380:8 <b>looked (4)</b> 372:23 378:24 396:21 405:23 <b>looking (5)</b>
---	--	---	---	--

325:9 326:19 337:8 357:24 372:3 <b>lost (9)</b> 277:5,7 293:9 362:15 362:17 373:17,25 382:10 384:16 <b>lot (2)</b> 308:7 425:24 <b>low (5)</b> 345:24 346:6,14,25 349:7 <b>lunch (2)</b> 400:21 402:15 <b>Lyons (4)</b> 270:24 271:10 431:6 431:21	300:21 301:13 302:4,6,10 319:23 320:2 323:25 324:22,25 325:14 379:25 430:16 <b>market (3)</b> 270:15 271:9 395:18 <b>marketing (1)</b> 351:22 <b>marriage (1)</b> 431:16 <b>Martinez (48)</b> 272:14 289:5 299:9 311:11 316:11 343:14 358:7,10 363:8 365:5 373:25 374:4,7 380:3 384:21,23 385:4,13 385:20,23 386:3,14 397:12 398:7,9 400:5 402:2,4,13 407:7 409:14,19 412:17,21 413:18 413:25 414:7 416:18 421:17 423:10 427:12,21 428:3,9 429:5,7 430:5,6 <b>Maslon (2)</b> 272:7 273:18 <b>material (2)</b> 274:20 371:2 <b>materials (2)</b> 351:3 425:16 <b>matter (10)</b> 286:13 295:6 311:17 326:14 346:16 347:3 352:19 416:11,22 431:16 <b>matters (1)</b> 410:9 <b>McConnell (4)</b> 283:4,6,14,20 <b>McConnell's (2)</b> 278:11 284:19 <b>McConville (1)</b> 283:4 <b>MDT000073RD (2)</b> 302:3 430:11 <b>MDT000332RD (2)</b> 302:3 430:11 <b>MDT071234RD (2)</b> 319:23 430:13 <b>MDT071290RD (2)</b> 323:24 430:15 <b>MDT071322RD (2)</b>	323:25 430:15 <b>mean (21)</b> 280:12 283:24 284:17 298:10 306:4 315:22 317:14 327:6 329:22 355:13,14 367:9 386:20 390:20 398:4 407:6 415:12 420:11 423:22 428:11,12 <b>means (3)</b> 389:21,25 396:12 <b>mechanism (2)</b> 347:10 349:3 <b>mechanisms (3)</b> 347:12 348:8,20 <b>media (1)</b> 353:4 <b>medical (1)</b> 393:23 <b>medication (1)</b> 278:15 <b>Medtronic (99)</b> 270:7,7,8,9,10 272:10 272:10,10,11,11 274:21 276:19 277:18 282:23 288:14 290:2 297:3 297:19 299:2,13,15 299:24,25 302:17 306:15 308:8 309:24 310:2,16,22 311:9,16 312:4,5 314:13 316:9 319:22 320:12,16 322:25 324:24 354:12,18,21 355:6 355:16 368:10 369:22 370:2,8 372:19 375:13 377:15,18,25,25 378:11,19 380:23 380:24,25 381:23 382:14 383:20 386:19,22,23 387:18 388:22 390:14,23 394:13 394:16,17,19,22 395:10,16 403:4 405:16 406:3,3,24 408:12 409:6 411:21 413:10 414:11,23 415:5,11 415:21,25 416:4 420:16 422:15	427:2 430:12,22 <b>Medtronic's (9)</b> 315:23 316:5 377:10 399:13 404:21 406:12,23 411:16 413:13 <b>membrane (2)</b> 389:18 408:20 <b>memory (2)</b> 338:22 424:4 <b>mention (2)</b> 363:12,18 <b>mentioned (1)</b> 426:4 <b>message (1)</b> 367:22 <b>method (1)</b> 340:25 <b>Michael (1)</b> 290:14 <b>middle (2)</b> 286:24 349:10 <b>mind (5)</b> 325:8 329:21 337:7 361:7,10 <b>Mini-Med (2)</b> 286:15 403:4 <b>MiniMed (4)</b> 270:7 272:10 324:24 430:22 <b>minimum (1)</b> 422:8 <b>Minneapolis (2)</b> 272:9 273:19 <b>Minnesota (1)</b> 272:9 <b>minority (1)</b> 286:3 <b>minute (3)</b> 299:22 300:16 393:19 <b>minutes (2)</b> 400:19,24 <b>misdelivery (1)</b> 346:15 <b>mislead (1)</b> 381:17 <b>missed (2)</b> 292:3,3 <b>missing (1)</b> 372:16 <b>mistaken (1)</b> 300:24 <b>misuse (1)</b> 354:5 <b>mode (1)</b> 345:4	<b>modes (1)</b> 345:6 <b>modified (1)</b> 274:10 <b>moisture (1)</b> 346:5 <b>mom (9)</b> 295:25 317:20 322:25 330:15 419:22 420:3 421:12,13 424:14 <b>moment (3)</b> 329:22 370:13 391:15 <b>Mon (1)</b> 283:6 <b>Monday (3)</b> 428:11,12 429:3 <b>monitoring (1)</b> 353:3 <b>Montal (2)</b> 283:6,6 <b>month (1)</b> 426:24 <b>morning (2)</b> 273:7,17 <b>mother (8)</b> 295:23 296:21 298:23 358:20,22 359:7 360:17,18 <b>motor (2)</b> 285:23,25 <b>mouth (1)</b> 357:4 <b>move (5)</b> 289:6 299:9,11 311:12 316:12 <b>multipage (4)</b> 301:24 323:21 430:9 430:14 <b>multiple (8)</b> 276:14,15 296:13 328:18 329:6 347:8 415:20 424:5
<hr/> <b>M</b> <hr/>				
<b>ma'am (2)</b> 358:13 364:15 <b>Madame (7)</b> 282:3 289:11 300:6 319:18 323:17 324:20 427:23 <b>majority (3)</b> 355:25 356:5 368:12 <b>making (1)</b> 376:2 <b>management (2)</b> 393:25,25 <b>manner (4)</b> 293:11 336:8 353:14 356:22 <b>manual (7)</b> 296:24 303:11 308:5 308:7,13 309:19 351:10 <b>manufacture (4)</b> 374:14 388:9,11 395:17 <b>manufactured (3)</b> 375:6,8,11 <b>manufacturer (3)</b> 353:14 354:3 422:3 <b>manufacturers (1)</b> 351:19 <b>manufactures (1)</b> 378:2 <b>manufacturing (7)</b> 369:14,18,22 370:2,4 386:23 403:14 <b>mark (4)</b> 300:23 301:10 319:19 323:18 <b>marked (16)</b> 282:10 289:12,16				
<hr/> <b>N</b> <hr/>				
<b>N (1)</b> 430:2 <b>name (4)</b> 273:4 283:8 389:12 432:2 <b>named (2)</b> 270:9 272:11 <b>Nancy (16)</b> 300:22 313:3,10 317:22 321:11 330:8,15,20,22				

330:8,15,20,22 331:9 332:25 333:11,20,24 334:5 420:6 <b>narrowed (1)</b> 342:19 <b>natural (7)</b> 296:24 297:22 298:12 298:20 368:2,14 418:20 <b>naturally (3)</b> 285:21 287:4 329:13 <b>nature (1)</b> 351:5 <b>nauseam (1)</b> 411:2 <b>necessarily (3)</b> 353:15 417:16 420:6 <b>necessary (5)</b> 338:3 341:2 386:25 423:3,5 <b>necessity (1)</b> 314:17 <b>need (7)</b> 355:23 363:20 366:7 395:8 417:18,19 424:11 <b>needed (15)</b> 274:15 279:17 291:13 295:2 297:7 311:25 341:4 376:20 383:18 387:19 404:4,5,9 415:22 416:2 <b>needs (3)</b> 297:12 426:5,23 <b>negative (1)</b> 348:14 <b>neither (2)</b> 276:5 375:5 <b>never (12)</b> 278:12,19 299:2 317:20 386:2 412:22 413:5 419:21 420:2 423:16,23 424:6 <b>new (9)</b> 271:16,17,18 272:4 424:16 427:8 431:8 431:9,9 <b>newcomer (1)</b> 281:10 <b>night (1)</b> 349:10 <b>normally (1)</b> 329:13	<b>norms (1)</b> 329:11 <b>Notary (3)</b> 271:17 431:9 432:25 <b>note (14)</b> 281:4 306:22 308:23 309:2 310:6,9 339:23 345:10 353:18 371:2 398:12,12 399:24 425:22 <b>noted (7)</b> 323:3 331:5 358:2 370:11 391:4 392:21 429:14 <b>noticed (1)</b> 326:2 <b>notices (1)</b> 420:20 <b>noticing (1)</b> 419:6 <b>notion (1)</b> 318:25 <b>number (41)</b> 282:5 288:20 289:13 289:21 297:17 300:7 324:3,6 327:19 334:23 335:4 350:6,11 396:11,17 398:23 398:24,24,24,24,25 398:25,25,25 399:2 399:2,2,3 402:7,11 402:16 408:11 422:20,21,23 424:7 424:22 425:10 429:12 430:8,17 <b>numbered (1)</b> 306:25 <b>numbers (5)</b> 302:3 323:24 422:14 430:10,15 <hr/> <b>O</b> <hr/> <b>o'clock (11)</b> 295:17,18 333:2,12 333:17,22,25 334:4 349:15,15,16 <b>object (15)</b> 289:5 299:9,10 311:11 316:11 344:13 397:9,11 398:4 407:4 410:23 412:2 415:15 420:8 423:17 <b>objecting (2)</b>	409:16,17 <b>objection (21)</b> 281:4 289:7 296:9 298:8 308:23 310:10 318:16,18 322:6 339:24 345:10 353:19 376:7 397:11 398:13 399:25 407:19 409:11 410:23 413:3 425:23 <b>objectionable (1)</b> 422:21 <b>obtained (2)</b> 337:9 375:12 <b>obvious (3)</b> 316:14 348:10,13 <b>obviously (1)</b> 302:23 <b>occur (4)</b> 309:12 346:17 347:13 396:18 <b>occurred (3)</b> 315:19,25 316:2 <b>offer (1)</b> 378:6 <b>offered (1)</b> 344:17 <b>offhand (4)</b> 338:16 351:9 370:5 416:10 <b>offices (1)</b> 271:8 <b>official (1)</b> 352:21 <b>oh (9)</b> 273:9 300:20 301:21 325:5,24 357:16 371:16 393:2 412:16 <b>okay (170)</b> 273:22 274:9,13,18 275:17 276:3,19,23 278:7,20 279:7 280:10,22 281:24 283:12 284:16,22 285:17 288:25 289:3,24 290:22 293:2,3,7,8 295:15 296:4,15 299:20 300:5,25 301:8,17 302:6 303:3,12 305:8 306:4,14 307:11 312:3,14,21 313:6,18 315:6	318:2 320:15,20 321:5,17 322:4,13 323:4,16,16 324:18 325:17,24 326:9 327:18 328:2,11 329:23 330:3,7,12 331:13,17,17 332:22 333:19 334:2,7,11 336:18 337:15 338:5,24 341:17 342:21 345:2 346:22 348:25 350:15,25 352:10,18 356:14 357:7,16 358:4,12 359:16 360:19 363:9 364:11,16 366:12 367:13 369:7,12 370:18 371:8 372:2 373:19 374:4,12,16 375:4 375:10 376:10 377:3,6,23 379:7 381:14,19 382:2,3 382:17,18,21 383:7 383:19 384:20 385:20 386:15 387:11,21 390:4,13 390:20 391:6 392:9 392:9 393:7,18 394:7 395:13 398:19 401:24 403:5 404:17 405:11 406:9,14 407:7 408:4,9 410:13 411:15 413:4,23 415:2,17 415:24 416:6,11 417:21 419:2 421:17 423:6 424:8 425:6 427:12 428:4 428:8 429:6 <b>once (4)</b> 330:14,18 414:15 416:15 <b>ones (5)</b> 283:11 329:21 354:17 371:5 377:25 <b>online (4)</b> 321:15 322:3 323:2 427:10 <b>online-pump (3)</b> 322:21 323:9 324:13 <b>Oops (1)</b> 393:3 <b>open (4)</b>	316:14 320:22 348:10 348:13 <b>Opening (1)</b> 320:23 <b>opine (4)</b> 280:23 291:20 296:7 342:17 <b>opined (2)</b> 292:14 310:15 <b>opinion (26)</b> 275:6 280:16 283:19 295:8 299:8 304:20 306:14 310:18,25 311:15 315:12,16 338:24 342:14 351:13 357:8 373:4 376:24 384:13 385:19 401:10 411:19 422:19 423:13 424:8 426:21 <b>opinions (11)</b> 274:11,24 295:6 299:23 373:7 378:6 398:15,16 399:17 416:23 425:18 <b>opposed (10)</b> 283:14 291:10 296:23 308:11 331:20 348:12 365:21 368:5 371:17 376:13 <b>order (1)</b> 381:23 <b>orient (2)</b> 364:21 367:19 <b>orientation (8)</b> 285:7 289:2 314:18 329:6 361:23 364:3 366:24 388:2 <b>original (4)</b> 278:2 359:25 375:18 383:7 <b>ought (1)</b> 362:23 <b>outcome (1)</b> 431:16 <b>over-delivery (1)</b> 346:7 <b>over-infusion (1)</b> 345:23 <b>overall (2)</b> 298:19 305:12 <hr/> <b>P</b> <hr/> <b>P (1)</b>
---	---	--	---	--

406:7 <b>P-cap (49)</b> 274:23 277:19 279:21 291:2,17 292:10,13 292:17 297:16 310:21 311:4 314:9 314:21 328:6 340:23 348:18 369:9,14,18,23 370:3 373:2,9 375:12,22 378:21 379:3 383:5 390:23 397:17 399:5,10,21 400:15 401:6,13,19 405:3,9,17 406:5 408:14,19,21 411:8 411:13,23 414:13 418:24 <b>p.m (8)</b> 334:25 363:5,6 385:8 385:9 402:8,9 429:14 <b>packet (1)</b> 330:10 <b>packets (1)</b> 314:15 <b>page (19)</b> 282:15,19 289:21 290:2 303:19 306:25 308:12 331:7 336:15,15,19 364:9 370:16 391:24 392:14 428:13 430:3,8,17 <b>pages (7)</b> 303:4 306:23 308:3,4 308:6 331:9 350:8 <b>paid (2)</b> 354:21 368:10 <b>paper (3)</b> 325:21 377:7 378:7 <b>Paradigm (30)</b> 290:6 301:25 302:15 324:24 354:18 355:17 370:17 371:3,17 372:9,19 372:20 373:3 374:23 376:14,16 376:22,23 378:22 387:3 388:21,21 391:22 395:10 399:6 403:2 408:2 427:4 430:10,22 <b>paragraph (8)</b> 282:18,22 289:25 364:12,18 365:15	365:16 367:7 <b>part (25)</b> 275:6 277:20 278:6 278:21 283:21,24 284:4 292:18 298:18 305:12 306:14 309:7 319:6 321:15 324:13 343:12 346:2 352:16 360:13 361:4 373:10 375:12 388:17 395:4 405:9 <b>partial (1)</b> 410:24 <b>participants (1)</b> 363:12 <b>participation (1)</b> 299:17 <b>particular (16)</b> 281:9 285:6,6 288:10 300:4 313:15 321:18 322:12 328:10,20 338:10 345:4 346:17 349:3 363:25 367:17 <b>particularly (1)</b> 353:23 <b>parties (1)</b> 431:15 <b>parts (1)</b> 386:21 <b>party (1)</b> 416:5 <b>pass (2)</b> 358:6 421:18 <b>patient (6)</b> 293:4 309:14 311:23 347:17 354:11 356:12 <b>patients (6)</b> 299:14,19 309:9,22 338:6,12 <b>pause (3)</b> 301:12 360:20 361:17 <b>pending (2)</b> 385:15 400:25 <b>Pennsylvania (7)</b> 270:15 271:10,15,19 431:3,8,10 <b>people (28)</b> 285:21,23 297:21 308:9 316:5 319:13 350:16,20 351:2,20 354:4,8 355:3 356:9 356:20 362:3	368:10,19 384:8 386:11 388:23 404:15 417:22 418:21 420:16 421:10 422:16 426:10 <b>percent (3)</b> 343:19 345:14 367:12 <b>percentile (2)</b> 355:21,22 <b>performed (6)</b> 277:18 331:11 403:22 403:23 408:12 409:4 <b>periodically (1)</b> 348:24 <b>person (13)</b> 285:9,12,12 316:16 363:19,25 364:19 367:2,18 384:24 405:24 423:25 425:4 <b>person's (2)</b> 362:6 424:3 <b>personally (2)</b> 350:18 357:18 <b>perspective (2)</b> 351:22,23 <b>Pg (1)</b> 432:5 <b>Ph.D (4)</b> 270:19 271:7 273:12 430:4 <b>phase (1)</b> 404:2 <b>PhD (4)</b> 289:15 429:18 430:20 431:11 <b>phenomenon (1)</b> 420:14 <b>Philadelphia (3)</b> 270:15 271:9 431:5 <b>phrased (1)</b> 339:25 <b>physically (5)</b> 278:3 314:7,10,11 321:7 <b>physicians (1)</b> 397:5 <b>pick (1)</b> 316:16 <b>pictograph (9)</b> 303:20,22,24 304:14 304:22 326:24 327:5,12,13 <b>picture (1)</b>	380:16 <b>pictures (2)</b> 383:10,12 <b>piece (1)</b> 325:21 <b>pieces (1)</b> 296:14 <b>place (1)</b> 419:8 <b>placed (2)</b> 278:13 413:3 <b>Plaintiff (2)</b> 270:5 272:4 <b>planning (1)</b> 383:16 <b>play (1)</b> 319:17 <b>please (9)</b> 273:6 283:17 372:14 381:20 386:16 403:20 412:9 413:6 428:2 <b>plus (1)</b> 420:22 <b>point (24)</b> 275:20 281:18 288:11 310:2 315:17,20,22 315:23 322:3 323:15 334:18 369:17 370:2 372:16,16 390:17 391:10 395:22 398:20 400:3 404:25 405:4,7 413:24 <b>pop (1)</b> 360:19 <b>popped (4)</b> 359:14 360:17,23 361:24 <b>population (6)</b> 279:4 342:10 354:11 355:5,11,19 <b>portion (6)</b> 307:7,9 339:13 342:9 385:16 386:5 <b>position (2)</b> 383:25 396:2 <b>possession (2)</b> 392:3 407:17 <b>possible (2)</b> 356:20 368:16 <b>possibly (2)</b> 287:21 356:23 <b>post (2)</b> 354:9 355:4	<b>posted (3)</b> 350:17,20 356:2 <b>posts (1)</b> 353:4 <b>potential (13)</b> 279:2,18 282:24 299:19 346:6 347:2 348:9 395:25 396:18 399:15 404:5 408:17 418:23 <b>potentially (2)</b> 288:21 309:12 <b>practice (3)</b> 291:6 352:4,9 <b>predicates (1)</b> 426:2 <b>prefer (1)</b> 287:5 <b>preferences (2)</b> 287:11 288:17 <b>prepare (1)</b> 274:6 <b>prescribed (1)</b> 355:16 <b>prescribing (1)</b> 309:21 <b>presence (2)</b> 294:24 340:11 <b>Present (3)</b> 272:8,15,20 <b>presented (2)</b> 275:15 280:21 <b>presume (2)</b> 314:25 315:5 <b>pretty (2)</b> 326:7 425:23 <b>prevent (4)</b> 291:14 292:8 349:12 411:12 <b>previous (2)</b> 301:19 426:13 <b>previously (8)</b> 273:4,13 282:10 289:12,16 324:21 324:25 430:16 <b>prime (24)</b> 292:15 297:2,18 333:16 346:9 348:12 349:8 371:21 372:4 376:15 377:15 378:12 388:3 389:3 389:7 390:10,16 397:7,14,20,21 418:17,24 420:13
---	--	--	--	---

418:17,24 420:13 <b>Priming (2)</b> 323:23 430:15 <b>printed (4)</b> 301:4 319:3,11 331:20 <b>printout (2)</b> 331:12,13 <b>prior (10)</b> 279:16 280:7 379:25 392:3 395:24 396:17 401:9 411:3 421:15 426:15 <b>probability (1)</b> 343:20 <b>probably (3)</b> 300:22 312:13 317:18 <b>problem (4)</b> 309:11 341:5 384:17 395:15 <b>problematic (2)</b> 279:21 309:16 <b>problems (1)</b> 279:2 <b>procedure (1)</b> 305:13 <b>process (11)</b> 274:22 275:12,15 313:17 320:16 361:9 364:5,23 369:3 405:9 410:21 <b>processes (1)</b> 410:12 <b>produce (1)</b> 394:18 <b>produced (5)</b> 276:18 302:11,17 356:6 380:23 <b>produces (1)</b> 288:20 <b>product (24)</b> 319:6 351:19,23 352:25 353:7,13 354:5 387:13,14 388:8,17 394:14,19 395:17 403:13,14 403:15,16 404:5,10 404:19 406:21 408:16 427:7 <b>product-related (2)</b> 351:17 353:5 <b>products (5)</b> 275:9 351:18,21 362:3 377:24 <b>professional (1)</b> 403:24	<b>professionally (1)</b> 368:10 <b>pronounce (1)</b> 283:7 <b>pronouncing (1)</b> 389:12 <b>proper (17)</b> 294:19,22 315:3 364:3,3,20 367:18 388:6 390:15 391:20 407:24 410:18 415:11,12 417:4,5,6 <b>properly (7)</b> 292:8 332:7 364:17 396:2 404:10 414:25 415:13 <b>provide (16)</b> 290:4 291:11 292:6 295:9 309:13 319:10 345:15 347:11 372:25 376:25 387:7,8,12 394:18 395:13 426:18 <b>provided (43)</b> 276:8 284:4 294:18 295:7,11,14 299:18 310:4 311:20,24 312:5 315:14 318:3 318:10,17 319:8 321:12,21 325:15 325:16,18 326:8 337:13 338:6 347:22 356:12 376:21 377:15 378:12 384:5,7 386:9,11 387:2,17 387:20 388:19 391:8,10 393:17 394:19 425:17 426:23 <b>provider (1)</b> 337:23 <b>providers (1)</b> 337:14 <b>provides (6)</b> 299:13 308:8 337:22 354:3 371:24 377:25 <b>providing (4)</b> 369:23 371:19 427:3 427:5 <b>provision (1)</b> 311:4 <b>public (8)</b>	271:17 389:19,21,24 389:25 396:9 431:9 432:25 <b>publications (1)</b> 352:20 <b>published (1)</b> 393:21 <b>pull (1)</b> 304:8 <b>pulled (3)</b> 338:22 347:19 379:14 <b>pulls (1)</b> 358:25 <b>pump (38)</b> 299:13 300:2,8 302:12,15,25 309:3 309:5,19,24 320:7,7 321:7,8,15 322:2,25 351:3,7,10 374:18 374:20,23 375:2,6 375:21 376:22,23 379:9,11 381:8,10 381:23,25 387:3 405:23 421:3 425:12 <b>pumped (1)</b> 278:14 <b>pumps (3)</b> 302:2 355:6 430:10 <b>punctured (1)</b> 333:8 <b>purpose (1)</b> 286:17 <b>purposes (2)</b> 382:6,15 <b>put (10)</b> 293:20 317:9 376:6 384:11 386:13 395:17 399:20 408:10 412:6 425:24 <b>puts (1)</b> 292:9 <b>putting (3)</b> 357:3 371:20 383:22	344:14,18 345:12 345:18 346:21 352:2,11 353:24 355:2,15,20 357:5 357:13 359:21 360:2 365:3,5 371:9 373:16 374:8 377:7 378:4 383:8 385:14 385:18 386:2,4,15 386:16 391:25 394:12 400:7,10 401:2,3,15,22 409:12,18 410:13 412:25 413:5,7,17 413:24 414:3,16 416:19 418:3 421:24 423:11 425:9 <b>questions (5)</b> 335:8 398:13 410:10 427:14,17 <b>quick (1)</b> 389:10 <b>Quick-set (2)</b> 391:22 408:2 <b>quite (7)</b> 281:6 303:9 304:19 346:18 351:15,25 352:3	<b>Rachel's (2)</b> 416:24 419:22 <b>range (1)</b> 422:7 <b>RDR (2)</b> 270:24 431:21 <b>re-asking (1)</b> 410:7 <b>reached (1)</b> 413:23 <b>read (28)</b> 290:2 306:19,21 307:6,9,9,14,16,17 307:20,25 308:6,12 308:19 330:5,13,17 339:12,14 351:2 362:11 385:14,17 385:23 386:6 423:15 424:10 432:5 <b>readers (1)</b> 297:7 <b>reading (2)</b> 392:6 423:16 <b>Reads (1)</b> 432:5 <b>real (1)</b> 389:10 <b>realize (1)</b> 281:9 <b>really (10)</b> 286:12,24 293:21 306:9 371:21 385:21 399:25 400:2 412:8,12 <b>Realtime (4)</b> 271:12,12 431:6,7 <b>reason (5)</b> 276:20 290:25 309:11 309:13 432:5 <b>reasonable (6)</b> 309:25 310:15 311:9 311:16,17,22 <b>reasonably (1)</b> 310:3 <b>recall (23)</b> 274:25 312:6,8,9,11 313:13,14 320:21 321:9,10,16 325:13 325:16 326:3 351:6 351:9 357:23,25 389:22 397:6 407:23,25 421:12 <b>receive (4)</b> 322:4 347:15,17,19 <b>received (9)</b>
---	---	--	--	--

321:25 322:9,11 356:10,15,23 357:6 381:21 425:15 <b>recess (5)</b> 277:12 334:24 363:5 385:8 402:8 <b>recognize (1)</b> 396:8 <b>recognizes (1)</b> 352:22 <b>recommended (1)</b> 393:16 <b>record (15)</b> 277:8,11 302:20,21 334:22 335:3 339:13 373:23 376:7 385:11,16 386:5 402:6 413:3 431:12 <b>recorded (1)</b> 297:18 <b>records (2)</b> 396:10 420:17 <b>rectification (1)</b> 347:10 <b>redo (2)</b> 346:20 416:4 <b>reduced (1)</b> 431:13 <b>refer (2)</b> 358:16 383:4 <b>reference (3)</b> 350:5 352:25 369:19 <b>referenced (1)</b> 350:11 <b>referencing (3)</b> 282:24 354:24 355:24 <b>referred (2)</b> 381:22 382:14 <b>referring (6)</b> 283:5 354:14 364:7 382:5,23 424:12 <b>refers (1)</b> 381:8 <b>regard (3)</b> 315:16 369:3 373:8 <b>regarding (13)</b> 285:25 297:13 308:17 313:15 322:19 328:10 335:10 345:16 350:21 373:4 387:13 398:16 410:10 <b>regards (2)</b> 308:15 353:5 <b>Register (1)</b>	394:2 <b>Registered (2)</b> 271:11 431:6 <b>regress (2)</b> 426:13,14 <b>regular (1)</b> 316:17 <b>regulation (2)</b> 394:4,6 <b>regulations (3)</b> 393:2,10 410:11 <b>regulatory (1)</b> 409:9 <b>reinforce (3)</b> 426:18 427:7,9 <b>reinforced (4)</b> 319:15 426:6,8,10 <b>reinforces (1)</b> 426:23 <b>related (17)</b> 295:13 308:21 339:10 339:21 340:12 371:19,21 372:4,25 376:15 378:20 379:6 389:18 390:16 396:11,24 431:15 <b>relates (2)</b> 303:14 369:4 <b>relating (1)</b> 304:6 <b>relationship (1)</b> 288:11 <b>relative (1)</b> 364:4 <b>relatively (1)</b> 424:16 <b>relevant (1)</b> 396:24 <b>reliance (1)</b> 309:23 <b>relied (9)</b> 298:3 351:13 352:14 352:15 387:18 409:5 414:23 424:10 425:19 <b>rely (11)</b> 299:25 306:16 310:3 310:7,16 311:10 384:6 386:9 387:2 406:22 415:21 <b>relying (13)</b> 283:13 290:14 296:23 310:11 311:7,18 388:20 400:17 408:5 418:16	420:22 423:16 424:13 <b>remem (1)</b> 393:15 <b>remember (6)</b> 307:21,25 308:12 321:13 357:2 391:21 <b>removal (4)</b> 275:20 303:14 326:21 328:15 <b>remove (12)</b> 281:3 285:10,13 288:6 296:2 298:21 304:9 315:3 327:20 348:15 358:21 408:17 <b>removed (20)</b> 275:22 277:21 278:5 278:15,17,19 279:11 280:4 291:3 295:20 296:16 303:25 304:15,24 327:2 340:8,16 341:4,9,13 <b>removes (1)</b> 365:23 <b>removing (10)</b> 287:2 297:23 312:23 317:10 320:17 342:6 356:21 368:24 369:6 420:14 <b>rendered (1)</b> 290:6 <b>repeat (1)</b> 419:24 <b>repeated (1)</b> 360:10 <b>repetitive (1)</b> 319:12 <b>rephrase (7)</b> 283:17 310:13 335:15 340:6,13 344:21 353:23 <b>report (41)</b> 274:25 282:5,15,16 289:10,14,21 293:25 299:23 309:2 310:24 323:3 328:17 329:19 330:2 331:4 336:16 336:17 339:2 342:22 350:4,5 358:18 360:10 363:13 364:7,10	365:9 368:17 370:11 372:7 380:10 383:20 391:4 398:8,14,17 398:21 402:16 410:15 430:20 <b>reported (3)</b> 270:24 277:21 333:2 <b>reporter (44)</b> 271:11,12,13,14,16 282:3,12 289:11,18 292:21 300:6,25 301:15,18 302:6 305:24 319:18,25 323:18 324:4,5,20 325:4 327:8 339:14 343:16 352:5 362:19 373:17 385:13,17 386:6 413:20 427:23,24 428:4,8,11 429:4,6 431:6,6,7,8 <b>REPORTING (1)</b> 272:21 <b>represent (3)</b> 302:21 320:5 355:13 <b>representation (2)</b> 303:2 410:25 <b>representative (6)</b> 279:4 354:11 355:5 355:10,19 407:12 <b>represents (1)</b> 359:6 <b>request (1)</b> 289:23 <b>required (3)</b> 329:16 393:11 411:11 <b>requirements (1)</b> 404:3 <b>requiring (1)</b> 393:15 <b>research (2)</b> 354:8,23 <b>reservoir (223)</b> 275:13,21,22 277:21 277:23 278:4,14,16 278:17 279:9,11,19 280:3,23 281:3 284:25 285:10,14 287:3,3,20 288:6,7 288:12 290:6 291:3 291:3,14,16,21 292:9,12 295:19,20 296:8,16,17 297:4,5 297:7,15,23 298:21 299:7 303:15,18,25	304:2,7,14,16,23,25 307:22 310:21 311:3,14 312:24 313:16 314:8,8,20 315:3 316:4 317:10 318:11 320:17 323:20,23 324:12 324:22,25 326:22 326:25 327:3,14,21 327:22 328:5,15,23 329:4 330:25 332:7 333:5,7 335:11,19 336:8 338:19 339:3 339:8,19 340:9,16 340:17 341:8,9,13 341:19 342:7,25 344:5 346:6 348:16 350:22 356:21 358:19,22,25 359:3 359:8,11,13,23 360:3,8,15 361:15 361:18 363:15,22 364:5,22,24 365:12 365:18 366:20 367:4 368:3,23 369:5 370:17,22 371:4 372:9,10,20 373:2,9,14 374:10 374:14,21,23 375:3 375:8,22 376:14,16 376:19 377:11 378:21,22 379:3,11 381:10,24 382:6,7,8 382:14,16,22,24 383:4,5 384:7 386:10 387:13,25 388:7,11,12,21 391:2 394:15 396:3 396:5,6,19 399:7,12 399:14 400:10 401:14 403:2 404:21,23 405:3,13 405:18,20,22 406:5 406:8,17,18 408:13 408:15,18 410:20 411:16,22 413:14 414:12 418:9,11,13 418:24 419:5,7,8,10 419:17,19 420:15 421:5,8 424:11 425:13 430:15,22 <b>reservoir's (1)</b> 310:19 <b>reservoirs (3)</b> 325:12 357:22 427:4 <b>resources (1)</b>
---	---	--	---	--

422:10	332:14,16 333:13	<b>saying (18)</b>	303:5,21 304:10	295:17 296:23
<b>respect (16)</b>	336:11 338:13	288:9 296:2 321:24	336:21 337:8 340:6	303:16 304:18
312:23 313:11 321:10	340:5 345:20	357:2 359:5 361:20	349:6,25 357:20	310:21 311:7
364:21 369:19	348:25 350:3 355:7	361:21 390:13	358:2 362:6 364:14	313:16 332:6
371:24 377:13,15	358:14 359:19	392:10,12,16 403:5	368:25 374:3	333:12,22 347:21
378:12 397:25	360:9 361:5,6,12	403:11 406:9,14,19	379:11 381:6,10,15	349:8,21 354:19
410:2,9 411:22	363:17 366:2,23	417:13 423:3	381:16,18 389:9	355:17,17 369:15
414:12 421:14	367:15 370:6 372:5	<b>says (14)</b>	421:20 422:23	369:24 370:7,9,17
425:11	373:11 377:17	276:19 286:20 304:6	423:21	370:20,23 371:4,15
<b>respond (1)</b>	378:14 380:14,19	305:2,9,17 347:23	<b>seeing (2)</b>	371:18,23 372:13
414:17	381:3 383:23	365:9,16 395:10	280:18 362:8	372:21 373:10
<b>responsibility (6)</b>	384:12 385:18	399:3 402:17	<b>seen (15)</b>	375:11,14,25 376:5
387:7,16 388:18,23	388:4,25 389:5	408:11 423:23	276:5 318:7,9 320:10	376:13,19 378:5,7
414:20,24	390:8 391:11,25	<b>school (1)</b>	320:11,15 324:8	378:10,16,21 379:2
<b>responsive (1)</b>	397:8 398:11 399:3	323:2	337:4,5 359:4	379:5,8,10 380:9,13
397:11	399:9,14,16 400:25	<b>Schultz (63)</b>	374:25 419:5	380:17 381:8,9,20
<b>rest (1)</b>	403:19 414:14	272:7 273:7,16,18	420:19 423:23	381:22,23,24 382:9
305:14	416:13,24 417:13	276:25 277:7,15	424:6	382:12,14,16 383:3
<b>restating (1)</b>	421:18 422:18	281:13,19 282:3,13	<b>selected (1)</b>	383:11,13,17
281:5	425:5 426:20	289:7,11,19 292:2	422:17	388:12 390:25
<b>result (6)</b>	427:12,13 429:9	292:25 293:4 300:6	<b>Self-Help (3)</b>	391:20,23 392:5
291:5 296:18 345:6	<b>right-handed (1)</b>	300:13,19 301:8,10	323:19,22 430:14	394:23,25 395:2,4
362:6 410:17	286:5	301:13,17,21 302:8	<b>send (1)</b>	395:14 398:14
418:22	<b>risk (13)</b>	310:12 319:18	314:14	399:7 400:14 401:6
<b>resulting (1)</b>	391:3,12 392:2,18,19	323:17 324:20	<b>sending (1)</b>	401:7,19,20 402:25
399:4	393:24,25 407:15	325:5 326:6,10,16	390:24	403:17 404:20
<b>retread (1)</b>	411:21 413:9,12	326:18 327:9	<b>sense (2)</b>	405:8,12,20 406:5,8
274:24	414:10 415:6	334:16,19 335:6	345:8 347:6	406:17 407:24
<b>reverse (2)</b>	<b>Road (1)</b>	340:5 344:20	<b>sent (3)</b>	408:3,14 411:23
285:21 286:2	272:16	353:22 358:4	337:13 338:11 380:5	413:14 414:13
<b>review (3)</b>	<b>role (1)</b>	362:17 363:3,10	<b>sentence (7)</b>	421:4 425:14 427:3
354:16 357:17 423:15	375:20	373:20,24 397:9	283:9 305:2,9,22	427:8 431:12,17
<b>reviewed (18)</b>	<b>rule (2)</b>	400:7 412:16,20	306:12 364:13	<b>sets (8)</b>
274:5,6,13 321:18,21	293:17 343:18	421:23 423:6	365:14	311:5 330:11 354:10
321:25 322:2,5,11	<b>run (1)</b>	427:16,22,25 428:6	<b>separate (1)</b>	355:6 371:6 399:22
324:16 337:16	422:10	428:10 429:3,8	377:19	418:6 427:4
370:6 371:3 380:10	<b>Rx (2)</b>	430:5,6	<b>September (7)</b>	<b>Seventh (1)</b>
391:12 392:3,19	324:25 430:22	<b>screen (1)</b>	270:16 271:5 273:10	272:9
400:3	<b>S</b>	379:15	335:4 385:11	<b>severe (1)</b>
<b>reviewers (1)</b>	<b>S (1)</b>	<b>sealed (1)</b>	402:11 431:18	286:12
393:22	430:7	333:7	<b>sequence (1)</b>	<b>severity (1)</b>
<b>Reviewing (3)</b>	<b>SA (2)</b>	<b>search (2)</b>	296:3	309:17
370:15 391:16 393:20	270:10 272:17	351:16 368:8	<b>serious (1)</b>	<b>sheet (6)</b>
<b>revisit (1)</b>	<b>safely (1)</b>	<b>second (10)</b>	279:21	296:22 318:4,8,15
274:23	404:10	276:24 278:21,21	<b>service (2)</b>	330:24 432:1
<b>ridiculous (1)</b>	<b>safety (1)</b>	279:25 282:21	396:10,22	<b>shift (1)</b>
384:25	393:23	286:7 300:15	<b>Services (1)</b>	299:20
<b>right (80)</b>	<b>sample (1)</b>	336:18 364:12,13	278:23	<b>shifted (1)</b>
274:18 275:25 283:20	279:4	<b>seconds (1)</b>	<b>session (2)</b>	370:3
284:7,11 285:10,13	<b>Sapio (4)</b>	373:24	309:8,15	<b>shipped (16)</b>
285:20 289:4 294:9	270:24 271:10 431:6	<b>section (6)</b>	<b>sessions (4)</b>	275:9,24 279:8 280:2
300:3,5 301:4,7,11	431:21	303:6,13,17 309:4	309:8 312:17 313:21	282:20 283:10
301:20 302:9	<b>saw (5)</b>	310:24 353:9	314:5	284:22 302:23,24
305:21 315:19	296:2 336:8 368:11	<b>see (29)</b>	<b>set (106)</b>	320:7,8 321:7
322:20 323:11	368:12,13	274:14 276:25 290:10	279:24 283:10 284:9	325:11,19 370:7
324:11,15,18		295:24 300:20	290:7 291:14,21	376:23

<b>shipping (1)</b> 386:23	<b>skin (2)</b> 371:20 379:5	325:22 327:4,9 331:3,24 334:16 335:22 340:3 343:13,16 346:21 352:3,7,7 357:12,14 357:16 359:8 360:14 364:6 365:2 367:2 371:10 373:16 374:4 379:24 382:10 383:11 384:23 386:3 389:15 393:8 394:5 395:16 405:6 406:2 409:14,23 412:21 419:24 421:9	<b>SRU (1)</b> 270:7	304:8
<b>short (2)</b> 334:18 410:4	<b>SKLARSKY (88)</b> 272:2 277:5 281:4,17		<b>ss (1)</b> 431:4	<b>stream (2)</b> 372:18 403:15
<b>shorter (1)</b> 308:10	291:23 292:23 293:3,7 296:9 298:8 300:10,12,14 301:3 301:9,16,20,22 303:9 308:23 310:6 310:9 318:16,18 322:6 323:6 324:3 325:23,25 326:9,13 331:7 334:15,17 339:11,23 344:9,11 344:13 345:9 353:18 362:15,18 362:20,23 363:2 365:2 376:6 379:20 379:24 380:5,7 384:15,20,22 385:21 398:3,8,11 399:24 407:4,19 409:11,16 410:23 411:25 412:5,11,19 413:2,15,19,22 414:6,14 415:14,19 416:15,20 417:7 420:8 423:17 425:3 425:8,22 427:19 429:2,9		<b>stand (1)</b> 398:18	<b>Street (3)</b> 270:15 271:9 272:9
<b>show (2)</b> 280:14 320:16			<b>standard (1)</b> 355:13	<b>stressed (2)</b> 309:20 329:3
<b>showed (5)</b> 313:20 314:7,10 315:2 365:11			<b>standards (1)</b> 393:10	<b>strike (6)</b> 289:6 299:10,11 311:12 316:12 418:6
<b>showing (4)</b> 280:23 297:20 329:6 368:2			<b>start (2)</b> 327:10 373:12	<b>strong (2)</b> 285:19 286:5
<b>shown (2)</b> 281:12 420:16			<b>started (4)</b> 274:2 402:24 403:25 421:3	<b>studies (17)</b> 275:14 276:17 277:17 282:25 284:5,18 391:21 403:3,8,9 405:17 406:4,11 407:25 422:14,25 423:13
<b>shows (4)</b> 280:14 288:8 303:24 328:21		<b>sort (1)</b> 344:23	<b>starting (5)</b> 315:17,20,22,22 412:24	<b>study (26)</b> 275:4,4 277:20 278:3 278:22 282:22 284:2,3 354:13,15 403:21 406:16 407:15 413:10,13 414:10,10 415:5,6 422:4,6,15,17,22 423:4,23
<b>sic (2)</b> 333:17 419:8		<b>sound (2)</b> 373:18 400:22	<b>starts (1)</b> 316:10	
<b>side (1)</b> 280:6		<b>sounds (1)</b> 344:15	<b>state (4)</b> 271:16 295:22 368:22 431:8	
<b>sideways (5)</b> 365:18 366:10,18 367:22 368:4		<b>source (2)</b> 362:13 420:6	<b>stated (3)</b> 306:12 336:22 397:24	
<b>Signature (1)</b> 432:21		<b>sources (4)</b> 423:14 424:22 425:10 425:19	<b>statement (3)</b> 283:3 322:14 413:6	
<b>significant (1)</b> 342:9		<b>South (1)</b> 272:9	<b>statements (1)</b> 284:15	
<b>Silhouette (5)</b> 369:15 370:8 371:15 381:22 382:13	<b>Skype (1)</b> 412:23	<b>speaking (4)</b> 292:22 305:25 352:6 413:21	<b>States (5)</b> 270:2 271:14,17 431:7,9	<b>stumbling (1)</b> 312:19
<b>similar (4)</b> 337:12 338:18,23 424:2	<b>small (1)</b> 305:12	<b>SPECIALIST (1)</b> 272:21	<b>stating (1)</b> 420:20	<b>sub-step (1)</b> 328:21
<b>simple (1)</b> 288:2	<b>social (1)</b> 353:3	<b>specific (11)</b> 302:23 308:8,11 345:3,15,16 352:24 376:12 402:20 416:18 424:7	<b>stay (1)</b> 349:21	<b>subject (3)</b> 284:14 397:4,6
<b>simplest (2)</b> 384:9 386:13	<b>society (1)</b> 352:22	<b>specifically (14)</b> 321:20 322:8 352:11 367:7 370:23 372:13 375:24 376:4 378:9,14 411:12 425:13,21 426:7	<b>step (26)</b> 280:14,20,23 287:6 287:18,19 288:19 297:9 299:5 303:20 303:23 304:6 313:15 326:21,21 327:25 328:20,23 328:24,25 329:3,4 329:10 336:22 340:18 369:4	<b>subjects (1)</b> 275:7
<b>simultaneous (4)</b> 292:22 305:25 352:6 413:21	<b>sold (1)</b> 372:17			<b>submission (1)</b> 407:22
<b>single (1)</b> 280:20	<b>somebody (3)</b> 288:8 294:18 329:12			<b>submitted (5)</b> 369:16 391:13 392:4 393:13 407:18
<b>sir (5)</b> 368:18 376:10 409:20 414:19 416:22	<b>somewhat (2)</b> 296:10,11			<b>Subscribed (2)</b> 429:20 432:22
<b>sit (2)</b> 313:18 323:5	<b>soon (4)</b> 308:3 425:7 426:22 428:6			<b>subsequently (1)</b> 366:10
<b>sitting (1)</b> 280:15	<b>sor (1)</b> 325:20	<b>spilled (2)</b> 333:24 334:3	<b>steps (10)</b> 279:16 280:8,8,21 286:11 287:2,17 292:7 404:5 411:11	<b>substance (2)</b> 338:6 399:19
<b>six (5)</b> 333:2,12,22,25 334:4	<b>sorry (58)</b> 273:10 276:10,12 277:9 283:7 291:8 292:2,5,25 299:10 303:7 306:2,3 310:23 312:19 314:25 321:2	<b>spilling (3)</b> 333:3,21 357:21	<b>stop (1)</b> 276:24	<b>successfully (2)</b> 332:5,6
<b>skills (2)</b> 285:24,25		<b>spoke (2)</b> 274:7,11	<b>storyboard (4)</b> 323:19,22 324:12 430:14	<b>suffer (1)</b> 349:8
		<b>spun-off (1)</b> 353:9	<b>straight (1)</b>	<b>suffered (2)</b> 290:21 420:13
		<b>squirt (1)</b> 341:15		<b>sugar (6)</b> 345:24 346:7,15

347:2,24 349:22 <b>suggest (3)</b> 298:22 375:2 395:9 <b>Suite (2)</b> 270:15 271:9 <b>summary (2)</b> 275:10 295:10 <b>supplemental (4)</b> 282:5,16 350:4 364:10 <b>support (1)</b> 284:14 <b>supporting (1)</b> 298:11 <b>supposed (2)</b> 366:19 367:4 <b>supposedly (1)</b> 333:14 <b>sure (53)</b> 281:5 282:17 283:18 283:19 285:19 293:15 299:16 307:2 313:7 319:5 325:6 326:7 327:20 328:12 329:18,20 331:6 333:5 334:19 341:25 344:24 345:14,19 346:18 347:23 352:2,10 361:4 364:8 365:8 367:8 371:12 373:3 380:11 381:6 382:11 384:5 386:8 387:4,6,9 390:7 395:8 405:10 406:24 408:10 410:7 411:18 414:24 415:10,22 417:25 422:20 <b>surf (1)</b> 351:16 <b>surface (1)</b> 275:21 <b>Susan (3)</b> 283:4,13,20 <b>suspect (1)</b> 288:3 <b>sworn (5)</b> 273:4,13 429:20 431:12 432:22 <b>system (22)</b> 372:17,22 373:6 376:19,21 379:11 381:10,24 386:21 388:13,14,14,16,17 390:18,21,22 395:5	395:8 402:25 404:3 411:23 <hr/> <b>T</b> <b>T (3)</b> 295:4 332:8 430:7 <b>table (10)</b> 275:21 278:4,12,13 278:18,19 279:10 280:3,15,25 <b>take (14)</b> 288:5 315:17 334:14 334:17 348:15 360:18 366:19 380:6,8 385:2,5 402:2 427:25 429:10 <b>takes (1)</b> 358:24 <b>talk (1)</b> 336:11 <b>talked (6)</b> 285:15 305:14 312:13 368:5,16 419:15 <b>talking (17)</b> 274:20 282:19 365:15 366:23 374:21 384:19 387:23 389:2 397:3 399:10 402:15 403:17 404:19,20 405:11 405:12 411:16 <b>talks (1)</b> 358:17 <b>task (9)</b> 279:2 308:9,11 368:17 402:24 405:21 424:2,16 426:20 <b>tasks (3)</b> 331:11 423:25 424:2 <b>team (1)</b> 353:9 <b>Technical (5)</b> 384:14 393:4 394:9 412:10 424:25 <b>tell (17)</b> 286:8 287:11 305:19 309:5 327:17 345:14 361:11 362:2 364:9 367:10 370:19 375:18,23 388:4 392:25 402:20 426:3 <b>telling (1)</b> 306:10	<b>tells (8)</b> 294:10 346:24 366:6 366:6,6,6,25 367:3 <b>temporarily (2)</b> 291:2 345:22 <b>temporary (3)</b> 397:3,15,19 <b>ten (2)</b> 295:17 422:21 <b>tend (1)</b> 348:9 <b>tendencies (1)</b> 368:14 <b>tendency (2)</b> 319:13 426:10 <b>terms (10)</b> 321:17 322:20 323:4 323:8 334:13 382:23 384:3 412:3 417:21 422:20 <b>terrible (1)</b> 287:8 <b>test (3)</b> 275:7 276:5 409:2 <b>tested (7)</b> 275:12,13 276:14,16 278:10 283:11 406:6 <b>testified (22)</b> 273:14 313:3 317:22 321:11,20 330:16 330:20,22 331:9 332:15,18,25 333:11,20 334:7 335:13,16,23 391:18 398:6,10 412:7 <b>testify (1)</b> 392:12 <b>testifying (5)</b> 290:24 312:9,11 401:11 409:9 <b>testimony (51)</b> 274:14,15,24 281:5 283:3,8,13,20 284:13,19 295:25 298:15 307:16,23 308:16 317:15 318:20 321:13 322:18 326:3 330:8 330:13,21 332:9,22 335:25 336:3,7,10 387:11 389:8 390:9 391:23 392:17,18 392:19 408:5,6 410:25 411:5 413:8	414:4,5,18,19 415:7 419:12,13 420:7 421:2 431:12 <b>testimony's (1)</b> 392:15 <b>testing (12)</b> 275:19 391:19 392:22 402:18,21 403:7 406:20 407:23 408:23,24 410:18 411:9 <b>text (3)</b> 297:10 304:5 327:24 <b>thank (30)</b> 273:22 282:7,13 289:19 300:9 301:21 302:5 324:2 325:3,5 334:20 358:4,14 385:5 402:3,4 403:10 409:19 415:2 416:6 421:20 423:7 425:8 427:14,15,17,18 428:9 429:7,8 <b>Thanks (2)</b> 427:19,21 <b>thereabouts (1)</b> 277:18 <b>thereof (1)</b> 375:21 <b>they'd (1)</b> 287:5 <b>thing (9)</b> 281:7 311:22 315:25 321:10 348:25 391:17 397:14 423:20 427:5 <b>things (9)</b> 276:23 284:24 287:23 309:21 328:4,13,18 368:3 421:19 <b>think (57)</b> 274:17 275:2,18 277:3 284:12 285:22 293:18 296:10 297:19,25 298:18 300:23 301:3,4,6,11 312:4 313:4 316:2,10 326:10 328:16 330:15,20 342:19 345:17 346:8,19 348:22 355:20 357:3 358:5 362:14 363:10 367:8,12 372:15 373:17	374:8 377:12 380:4 382:20 383:2 384:16 389:25 392:7 399:20,25 400:4 405:21,23 412:12 418:2 419:2 422:8 423:5 428:10 <b>third (1)</b> 416:5 <b>THOMPSON (1)</b> 272:14 <b>thought (12)</b> 291:8,24 293:6,9 323:12 332:6 359:17 360:11,12 361:9,13 416:16 <b>three (6)</b> 348:3,7,9 349:15,23 426:25 <b>time (59)</b> 273:11 275:5,14 277:11 278:4 279:10 285:16 295:16 296:18 307:17,21 315:14 319:12 330:24 331:23 334:23 335:5,12,18,21 338:9,14 341:20 342:25 346:23 351:7,11 359:24 360:21 370:5 371:7 371:11 375:16 380:18 385:7,12 390:3,17,19 391:14 392:4 393:12 395:24 400:20 402:7,12 407:17 419:16,16 420:18 421:2 424:15 426:6 426:9,10 427:6,8 429:13,14 <b>times (5)</b> 412:13 415:20 420:12 423:14 424:9 <b>title (1)</b> 303:17 <b>today (7)</b> 274:7 313:18 323:5 324:9 350:10 410:7 411:3 <b>told (4)</b> 300:25 333:24 363:10 366:15 <b>tool (1)</b> 309:7
--	--	--	---	---

<b>top (20)</b> 279:19 291:16 292:9 292:12 297:8,14 299:6 311:2 314:20 328:5 338:19 341:8 341:19 342:25 346:5 360:23 368:5 399:11 400:9 401:14	364:4,22,25 365:13 365:17,23 366:9,11 366:20 367:5,21 368:25 369:6 396:4 410:20 418:10,14 419:9,18 421:5,8	<b>ultimate (1)</b> 389:22	405:10 408:15 421:12	410:16 411:24 413:11 414:8 415:7 427:2
<b>topic (7)</b> 295:13 299:21 308:17 318:21 335:8 409:22,24	<b>transferred (2)</b> 278:16 328:6	<b>ultimately (1)</b> 397:5	<b>understands (3)</b> 340:2 414:16 423:21	<b>Unomedical's (9)</b> 290:3,3 299:16 375:20 379:8 387:14 388:8 402:17 408:16
<b>topics (2)</b> 409:25 410:3	<b>trial (1)</b> 383:9	<b>unclear (1)</b> 310:10	<b>understood (5)</b> 307:17 318:14 322:16 375:17 378:24	<b>Unomedical/Medtr...</b> 420:17
<b>tops (1)</b> 357:21	<b>tried (2)</b> 287:23 376:11	<b>uncontrolled (2)</b> 290:16 293:13	<b>undertaken (1)</b> 274:22	<b>unreasonable (2)</b> 299:24 306:15
<b>totality (2)</b> 280:20 297:25	<b>trouble (1)</b> 344:19	<b>under-delivery (6)</b> 346:11 347:9,16,18 347:20 348:4	<b>unexpected (1)</b> 293:13	<b>unreasonably (3)</b> 290:5,7 395:18
<b>traditional (1)</b> 329:11	<b>true (4)</b> 313:22 321:22 355:8 431:12	<b>under-dispensing (1)</b> 411:7	<b>Unfortunately (1)</b> 317:16	<b>upright (2)</b> 341:12 408:18
<b>trailed (2)</b> 353:21 384:16	<b>try (5)</b> 308:12 344:20 346:22 376:2 420:9	<b>underneath (1)</b> 418:13	<b>unintended (1)</b> 399:4	<b>upside (3)</b> 363:20 366:7,17
<b>train (2)</b> 293:9 299:3	<b>trying (13)</b> 283:18 284:17 306:5 315:24 347:7 364:17 365:7 366:22 367:22,24 368:15 377:5 414:4	<b>underneath (1)</b> 418:13	<b>unit (7)</b> 358:20,23,24 359:13 363:20 365:19 366:7	<b>usability (27)</b> 275:4 276:16 277:17 278:3 282:21 284:2 284:2,3,18 403:3,9 403:10,21 405:16 406:4,11,16 407:15 408:24 411:20 413:10,13 414:9 415:5 422:4,14,15
<b>trained (6)</b> 298:24 299:18 312:22 314:4 350:20,21	<b>TSG (1)</b> 272:21	<b>understand (53)</b> 283:16 284:17 286:4 292:18 299:22 304:20 305:23 306:7,17 307:14 308:24 315:7 318:14,19 330:19 331:14,22 332:2,16 340:4,14 344:10 345:11 359:5,20 365:9 369:12 370:20 372:6 373:12 374:9,12,16 375:5,10 377:8,18 377:20,21 379:8 382:21 383:24,25 388:10 389:20 401:10 404:17,24 405:15 406:25 415:7 420:9 422:18	<b>unnatural (1)</b> 329:10	<b>use (27)</b> 275:3,4 276:11 285:6 285:13 287:10 288:9 291:13 311:14 319:6 326:15 330:18 335:11 351:4,19 352:22 362:3 387:5 391:20 393:23 404:5,10 407:24 417:22 424:18 425:12 427:6
<b>trainer (2)</b> 298:25 314:16	<b>tube (1)</b> 338:19	<b>understanding (41)</b> 280:20 285:11 293:10 295:5 296:20 299:12,15 309:6 312:16 313:7,9 330:4,6,17 331:16 332:4 333:10,16,20 333:23 336:6 338:16 341:11 344:17 346:19 363:24 364:16 369:10 371:5 375:19 378:23 380:15 389:6 392:24 394:7 396:16,20 397:13	<b>unno (1)</b> 299:8	<b>user (71)</b> 279:4 281:2 285:5 287:4,10 288:18 294:10,11,25 297:11,11 300:2,8 302:2,11,22 303:5,6 303:13 304:23 305:6 306:11,16,19 306:20,22 307:7,10 308:21 309:3,5,25 310:17,19 311:6,6 311:10 316:17 328:3,14 342:10 346:25 347:22 348:4,8,21 349:20 351:3,7,10 353:12 355:11 356:15
<b>trainers (4)</b> 299:4,18 309:20 314:15	<b>tubing (2)</b> 347:20 375:12		<b>unomedical (1)</b> 415:4	
<b>training (33)</b> 299:13 309:7 311:8 312:6,25 313:12,21 314:5 315:14 318:5 319:2,5,6,9,10,12 319:14,15 322:21 323:9 324:13 350:23 362:7,12 425:15 426:4,9,11 426:17,22,23 427:8 427:9	<b>turn (5)</b> 289:9,20 303:4 304:7 350:3		<b>Unomedical (84)</b> 270:10,11 272:17,17 288:15 299:2,13 310:22 311:9,17 316:10 369:8,13,18 369:23 370:4 372:18 373:13 374:9,13,17 375:2,5 375:11 376:18,24 377:14,19,24 378:11,18 380:24 382:5,19,23 383:10 383:20 384:2,13 385:19 386:17,22 386:22 387:12 388:5,10 389:6,17 390:9,14,24 391:12 392:2 393:11 394:17,21 395:6,12 395:25 396:16,21 397:25 398:17,21 402:22 403:6,21 405:2,7 406:10,15 406:19 407:16 408:7,12,24 409:2,4	
<b>transcript (4)</b> 274:6 301:19 428:2 428:13	<b>turned (2)</b> 366:10 367:21			
<b>transfer (48)</b> 278:5,13,17 288:6 297:24 304:7,9,24 327:2,15,21 333:8 339:9,20 340:16 341:13 342:7,8 356:21 358:25 359:11,23 360:3,15 361:15,18 363:22	<b>two (16)</b> 272:15 312:17 348:19 349:15,18,18,22 355:14 365:16 373:24 377:21 395:20 419:20 421:9 422:13 426:24			
	<b>typ (1)</b> 294:14			
	<b>type (1)</b> 423:4			
	<b>typewriting (1)</b> 431:13			
	<b>typically (5)</b> 285:22 286:4 294:17 308:9 426:7			
	<b>U</b>			

365:17,22 366:5 368:23 379:9,9 381:8,8,23 382:5,24 396:18 399:12 417:23,24 423:14 424:16 430:10 <b>users (16)</b> 277:20 321:8 351:17 353:6 354:19 355:5 355:16,18 363:14 364:19 396:2 397:5 399:6 408:17 422:6 425:20	341:10,12,14,16 342:8 348:15,16 358:24 359:3,8,9,22 360:2,8,14 361:14 361:17 363:21 364:4,21,24 365:12 365:17,23 366:8,11 366:16,19 367:3,11 367:19,21 368:24 369:5 382:7 387:25 387:25 396:3,5 408:19 410:19 418:11,12 419:8,17 419:20 420:15 421:6,7 <b>video (38)</b> 272:21 273:2 277:11 293:5 320:3,6,10,11 320:13,15 321:6,18 321:21 334:22 335:3 353:13 358:17,19 359:5,6 360:6 361:22 362:25 363:4,19,25 364:2,19,20 365:8 365:11 366:5,6,25 367:2,18 385:6 402:6 <b>Videoconference (2)</b> 272:8,15 <b>VIDEOGRAPHER...</b> 273:2,9 277:10,14 334:21 335:2 362:24 363:4,7 373:22 385:6,10 402:5,10 429:11 <b>videos (40)</b> 297:20 298:5,13,16 321:10,12,14 322:2 323:13 332:12 350:6,11,17,20 351:14 352:14,15 352:23 354:9,17,24 354:25 355:4 356:2 357:17,21 358:16 363:12,18 365:16 365:22 367:25 368:7,11,12,19,19 368:23 420:19 427:11 <b>videotaped (2)</b> 270:19 271:6 <b>view (9)</b> 279:12 322:23 336:25 366:4 415:10,12 417:4,6,15	<b>viewed (5)</b> 283:15 322:15,16,23 323:10 <b>viewer (5)</b> 363:19 366:5,25 367:3,10 <b>viewers (1)</b> 364:20 <b>Vigilante (202)</b> 270:19 271:7 273:1,5 273:8,12,17,23 274:1 275:1 276:1 277:1,16 278:1 279:1 280:1 281:1 282:1,4 283:1 284:1 285:1 286:1 287:1 288:1 289:1,9,15,20 290:1 291:1 292:1 293:1 294:1 295:1 296:1 297:1 298:1 299:1 300:1,7,11 301:1 302:1,9 303:1 304:1 305:1 306:1 307:1,4 308:1 309:1 310:1,14 311:1 312:1 313:1 314:1 315:1 316:1 317:1 318:1,23 319:1,25 320:1 321:1 322:1 323:1 324:1,5,21 325:1,6 326:1,19 327:1,11 328:1 329:1 330:1 331:1 332:1 333:1 334:1 335:1,7 336:1 337:1 338:1 339:1 340:1 341:1 342:1,11 343:1 344:1 345:1 346:1 347:1 348:1 349:1 350:1 351:1 352:1 353:1,25 354:1 355:1 356:1 357:1 358:1,5,11,15 359:1 360:1 361:1 362:1 363:1,9 364:1 365:1,7 366:1 367:1 368:1 369:1,7 370:1 371:1 372:1 373:1 374:1 375:1 376:1 377:1 378:1 379:1 380:1 381:1 382:1 383:1 384:1 385:1 386:1 387:1 388:1 389:1 390:1 391:1 392:1 393:1 394:1 395:1 396:1 397:1	398:1 399:1 400:1 401:1 402:1,14 403:1 404:1 405:1 406:1 407:1,8 408:1 409:1 410:1 411:1 412:1,25 413:1 414:1 415:1 416:1,7 417:1 418:1 419:1 420:1 421:1,25 422:1 423:1,12 424:1 425:1 426:1 427:1,17 428:1 429:1,18 430:1,4,20 431:11 <b>Vigilante's (1)</b> 400:8 <b>Vigilante-10 (2)</b> 289:14 430:20 <b>Vigilante-11 (2)</b> 282:8 430:18 <b>Vigilante-17 (2)</b> 324:23 430:22 <b>Vigilante-18 (2)</b> 301:24 430:9 <b>Vigilante-19 (2)</b> 319:21 430:12 <b>Vigilante-20 (2)</b> 323:21 430:14 <b>voice (1)</b> 353:21 <b>VOLUME (1)</b> 270:1 <b>voluntary (1)</b> 397:6 <b>vs (3)</b> 270:6 319:22 430:12	324:1 325:1 326:1 327:1 328:1 329:1 330:1 331:1 332:1 333:1 334:1 335:1 336:1 337:1 338:1 339:1 340:1 341:1 342:1 343:1 344:1 345:1 346:1 347:1 348:1 349:1 350:1 351:1 352:1 353:1 354:1 355:1 356:1 357:1 358:1 359:1 360:1 361:1 362:1 363:1 364:1 365:1 366:1 367:1 368:1 369:1 370:1 371:1 372:1 373:1 374:1 375:1 376:1 377:1 378:1 379:1 380:1 381:1 382:1 383:1 384:1 385:1 386:1 387:1 388:1 389:1 390:1 391:1 392:1 393:1 394:1 395:1 396:1 397:1 398:1 399:1 400:1 401:1 402:1 403:1 404:1 405:1 406:1 407:1 408:1 409:1 410:1 411:1 412:1 413:1 414:1 415:1 416:1 417:1 418:1 419:1 420:1 421:1 422:1 423:1 424:1 425:1 426:1 427:1 428:1 429:1 430:1 <b>wait (5)</b> 277:9 421:20 429:2,2 429:2 <b>wake (1)</b> 349:14 <b>want (35)</b> 274:18,23 282:16 283:12 287:17,18 288:25 289:2 301:2 302:18 305:21 313:7 325:6 328:12 329:17,19 334:12 347:11 348:8,20 349:12,14 351:24 352:10 365:8 370:22,25 377:17 377:17 378:3 381:17 385:2 397:10 422:19 428:5
<b>V</b>			<b>W</b>	
<b>vacuum (3)</b> 372:20,21,22 <b>validate (1)</b> 404:14 <b>variable (1)</b> 424:6 <b>variety (1)</b> 345:5 <b>various (1)</b> 398:15 <b>vast (2)</b> 355:25 356:4 <b>vent (4)</b> 345:23 397:3,15,19 <b>vents (18)</b> 290:19 291:2 292:16 292:17,19 293:14 311:4 344:8 346:10 397:17,22 399:5,10 400:15 408:21 411:8,13 418:24 <b>version (1)</b> 321:4 <b>versions (2)</b> 276:15 320:24 <b>versus (1)</b> 407:11 <b>vial (93)</b> 275:20 277:22,22 278:4,12,18 279:10 280:3,15,24 281:3 284:25 287:3,19,20 288:7,12 291:4 295:19 296:17 297:4,24 298:22 304:2,2,6,15,16,25 312:24 315:4 320:18 326:22 327:3,15,22 328:15 328:23 333:4 340:9 340:17,24 341:8,9				

<b>wanted (1)</b> 394:14	297:22 298:12,20 306:24,25 307:24 311:14 313:24 314:2 315:3,5 316:19 319:8 321:5 321:23 328:12 336:10 337:16 341:7 342:12 344:15 351:18 354:7 355:5,23 357:8 360:22 361:2 361:5,8,11 362:9 364:3,20 365:24 367:18 368:2,13,13 368:22 377:12 378:23,24 384:11 386:13 387:5,7 411:10 417:24 418:17 423:18 431:16	431:17 <b>William (9)</b> 270:19 271:7 273:5 273:12 289:15 429:18 430:4,20 431:11 <b>Williams (3)</b> 270:14 271:8 272:2 <b>wisdom (1)</b> 319:2 <b>withdraw (1)</b> 394:12 <b>witness (31)</b> 273:3 277:3 282:7 289:22 293:8 300:9 302:5 324:2 325:3 334:5,20 358:6 362:22 373:15,19 374:3 384:18 385:2 385:25 402:3 419:14 421:18,21 423:8,21 427:15,18 430:3 431:11,13,17 <b>Woodland (1)</b> 272:3 <b>word (1)</b> 343:24 <b>words (4)</b> 285:8 312:19 357:4 364:23 <b>work (1)</b> 273:25 <b>working (1)</b> 394:22 <b>world (2)</b> 280:13 286:3 <b>worries (1)</b> 371:12 <b>worst (1)</b> 280:13 <b>wouldn't (5)</b> 276:22 310:15 329:13 340:21 417:19 <b>write (2)</b> 282:22 290:2 <b>written (5)</b> 319:7 377:8 383:23 411:11 425:16 <b>wrong (10)</b> 286:19 295:24 310:24 310:24 330:21,22 344:14 368:13 416:16 422:13 <b>wrote (1)</b> 362:9	<b>X</b> <b>X (4)</b> 383:18 423:23 430:2 430:7 <b>Y</b> <b>Y (1)</b> 383:18 <b>yeah (95)</b> 276:7 281:20 283:5 290:14 291:8,18 292:5,18,23 293:8 293:21 294:14,17 295:11,21 298:10 300:13 301:3,9 302:14 303:17,19 303:24 306:3 307:8 307:15,23 308:16 309:2 310:12,18 311:20 312:16 314:6 315:10,21 318:20 321:9 322:10,18 326:6,16 327:24 328:9 331:8 331:24 332:3 335:22,25 337:21 338:15,17,21 340:3 340:20,21 341:11 341:21 343:3,14 345:9,13 346:18 353:22 356:11 357:2 359:12 361:10,25 362:18 363:3 369:25 371:16 374:25 376:11 378:18 383:16 384:4,22 386:7 392:6 393:14 396:20 398:16 402:23 411:5 412:19 417:8,17 418:15 419:11,21 421:9 422:22 423:22 <b>years (4)</b> 362:2 396:12,17,25 <b>Yep (2)</b> 334:20 373:21 <b>York (2)</b> 271:18 431:9 <b>YouTube (20)</b> 297:20 298:4,13,16 332:12 350:6 351:14 352:14,15 352:23 353:13 354:9,17,24,25	355:4,25 367:25 368:7 420:19 <b>Z</b> <b>Z (2)</b> 272:14 383:18 <b>0</b> <b>08002 (1)</b> 272:4 <b>1</b> <b>1 (4)</b> 282:15 334:23 398:23 399:3 <b>1:04 (1)</b> 385:8 <b>1:15 (1)</b> 385:9 <b>1:35 (1)</b> 400:19 <b>1:37 (1)</b> 402:8 <b>10 (4)</b> 289:13,21 405:21 422:13 <b>10:27 (2)</b> 270:16 273:11 <b>10:30 (1)</b> 349:6 <b>10:31 (2)</b> 277:11,12 <b>10:32 (2)</b> 277:13,14 <b>100 (3)</b> 343:19 367:12 423:2 <b>11 (3)</b> 282:5,16 350:4 <b>11:42 (1)</b> 334:24 <b>11:43 (1)</b> 334:23 <b>112521 (1)</b> 270:25 <b>12 (3)</b> 300:8,16,21 <b>12:01 (2)</b> 334:25 335:5 <b>12:36 (1)</b> 363:5 <b>12:37 (2)</b> 363:4,6 <b>12:38 (1)</b> 363:7 <b>13 (1)</b> 398:25
-----------------------------	---	--	---	---

<b>13:05 (1)</b> 385:7 <b>13:15 (1)</b> 385:12 <b>13:38 (1)</b> 402:7 <b>1300 (2)</b> 270:15 271:9 <b>14 (1)</b> 398:25 <b>14:37 (1)</b> 402:12 <b>15 (3)</b> 326:4,11 398:25 <b>15:10 (1)</b> 429:13 <b>1515 (2)</b> 270:15 271:8 <b>16 (3)</b> 282:9 399:2 430:19 <b>16th (1)</b> 282:6 <b>17 (11)</b> 301:6,22,22 324:22 325:10 326:5,7,11 326:17,20 399:2 <b>18 (6)</b> 301:2,11,23 302:7,10 399:2 <b>19 (8)</b> 289:16,21 300:24 320:3 321:7,19 322:15 430:21 <b>19102 (2)</b> 270:15 271:10 <b>19th (1)</b> 336:17 <hr/> <b>2</b> <hr/> <b>2 (3)</b> 335:4 364:9 402:7 <b>2:36 (1)</b> 402:9 <b>20 (5)</b> 323:18 324:4,6 400:19 422:9 <b>2000 (4)</b> 275:5 277:18 390:19 393:21 <b>2001 (2)</b> 390:19,19 <b>2002 (1)</b> 297:19 <b>2006 (2)</b> 369:22 375:12 <b>2009 (6)</b>	295:18 298:7 307:22 331:2 335:19 340:10 <b>2012 (2)</b> 390:3 396:9 <b>2013 (15)</b> 337:3,14,17,20 356:2 356:17,24 357:9 389:22 390:3,4 395:25 396:9,17 397:4 <b>2016 (15)</b> 270:16 271:5 273:11 282:6,9 289:16 335:4 336:17 385:11 402:12 429:22 430:19,21 431:18 432:23 <b>203 (1)</b> 331:9 <b>205 (1)</b> 331:9 <b>21 (2)</b> 336:15,19 <b>210 (1)</b> 272:3 <b>23 (2)</b> 270:16 271:5 <b>23rd (4)</b> 273:10 335:4 385:11 402:11 <b>242 (1)</b> 306:25 <b>250 (2)</b> 306:23 308:3 <b>250-page (1)</b> 308:13 <b>26th (1)</b> 431:18 <b>273 (1)</b> 430:5 <b>282 (1)</b> 430:18 <b>289 (1)</b> 430:20 <hr/> <b>3</b> <hr/> <b>3 (5)</b> 370:16 398:24 402:11 402:16 429:12 <b>3:10 (1)</b> 429:14 <b>3:11-CV-01229 (1)</b> 270:7 <b>30(b)(6) (1)</b> 407:12	<b>301 (1)</b> 430:9 <b>30326 (1)</b> 272:16 <b>319 (1)</b> 430:12 <b>323 (1)</b> 430:14 <b>324 (1)</b> 430:22 <b>3300 (1)</b> 272:8 <b>3560 (1)</b> 272:16 <b>358 (1)</b> 430:5 <hr/> <b>4</b> <hr/> <b>4 (3)</b> 350:8 398:24 408:11 <b>421 (1)</b> 430:6 <b>423 (1)</b> 430:6 <hr/> <b>5</b> <hr/> <b>5 (5)</b> 328:23,24 350:8 364:9 398:24 <b>500 (1)</b> 423:2 <b>501(k) (3)</b> 369:20 394:23 407:22 <b>510(k) (5)</b> 369:15 391:13 392:4 393:13 407:18 <b>522 (2)</b> 301:25 430:10 <b>55402 (1)</b> 272:9 <b>5th (1)</b> 355:22 <hr/> <b>6</b> <hr/> <b>6 (13)</b> 280:14 287:19 288:20 325:10 326:21 328:20,25 329:3,10 331:7 340:18 369:4 398:24 <b>60 (1)</b> 303:4 <b>61 (3)</b> 303:4,19 308:12 <b>67 (1)</b> 391:24	<hr/> <b>7</b> <hr/> <b>7 (1)</b> 329:4 <b>722 (3)</b> 301:25 302:15 430:10 <b>7a (1)</b> 336:22 <b>7th (3)</b> 337:14,17,20 <hr/> <b>8</b> <hr/> <b>8th (6)</b> 295:18 298:6 307:22 331:2 335:19 340:10 <hr/> <b>9</b> <hr/> <b>9 (4)</b> 303:20,23 304:6 398:25 <b>90 (1)</b> 272:9 <b>95th (1)</b> 355:21
--	--	---	---